# EVALUATION OF 3 DIMENSIONAL PLATES IN OPEN REDUCTION AND INTERNAL FIXATION OF SUBCONDYLAR FRACTURES

*A Dissertation submitted in*
*partial fulfillment of the requirements*
*for the degree of*

**MASTER OF DENTAL SURGERY**

**BRANCH – III**

**ORAL AND MAXILLOFACIAL SURGERY**


**THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY**
**CHENNAI – 600 032**

**2014 - 2017**

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This is to certify that the Dissertation entitled "**EVALUATION OF 3 DIMENSIONAL PLATES IN OPEN REDUCTION AND INTERNAL FIXATION OF SUBCONDYLAR FRACTURES***"* is a bonafide work done by **Dr.TRIVENI.P**, Postgraduate student (2014-2017) in the Department of Oral and Maxillofacial Surgery, under the guidance of **Dr.P.SRIMATHI, M.D.S.,** Professor, Department of Oral and Maxillofacial Surgery, Tamil Nadu Government Dental College and Hospital, Chennai – 600 003.

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# DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation titled **"EVALUATION OF 3 DIMENSIONAL PLATES IN OPEN REDUCTION AND INTERNAL FIXATION OF SUBCONDYLAR FRACTURES"** is a bonafide and genuine research work carried out by me under the guidance of **Dr. P. SRIMATHI, MDS., Professor,** Department of Oral and Maxillofacial Surgery, Tamil Nadu Government Dental College and Hospital, Chennai -600003**.**

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Last but not the least I would like to seek the blessings of the Almighty without whose grace this endeavor wouldn't have been possible.

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This agreement herein after the "Agreement" is entered into on this day _____ between the Tamil Nadu Government Dental College and Hospital represented by its **Principal** having address at Tamil Nadu Government Dental College and Hospital, Chennai - 600 003, (Hereinafter referred to as, the college")

And

**Dr.P.SRIMATHI**, aged 57 years working as Professor and Head of Department in Oral &Maxillofacial Surgery, at the college, having residence at Mylapore, Chennai. (Herein after referred to as the "Principal investigator")

And

**Dr. TRIVENI.P,** aged 31 years currently studying as Post Graduate Student in the Department of Oral & Maxillofacial Surgery, Tamil Nadu Government Dental College and Hospital, Chennai-03 (Herein after referred to as the "PG Student and co-investigator").

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2.

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20-02-2016

Ref: R.C No.0430/DE/2015 dated 03-10-2015 o/o Principal, TNGDC
Sub: IEC review of the research proposals,

Title of the work: Evaluation of 3 Dimensional Plates in Open reduction and internal fixation of subcondylar fractures

Principal Investigator: Dr. P. TRIVENI
II YR. MDS

Department : Department of Oral and maxillofacial surgery
Tamil Nadu Government Dental College & Hospital, Chennai-3

Thank you for submitting your research proposal , which was considered at the Institutional Ethics Committee meeting held on 17-10-2015, at TN Govt. Dental College and the documents related to the study referred above were discussed and the modifications done as suggested and reported to us through your letter dated 19-02-2016 have been reviewed.

The decision of the members of the committee , the secretary and the Chairperson IEC of TN Govt. Dental College is here under:

| | |
|---|---|
| Approved | Approved and advised to proceed with the study |
| Approved with suggestions | ---------- |
| Revision | ---------- |
| Rejected | ---------- |

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# ABSTRACT

## AIM

The purpose of this study is to evaluate the effectiveness of 3D plates in open reduction and internal fixation of subcondylar fractures.

## MATERIALS AND METHODOLOGY

A Prospective clinical and radiological study was conducted on five patients reporting at the Department Of Oral And Maxillofacial Surgery, The Tamil Nadu Government Dental College and Hospital, Chennai. Patients with subcondylar fractures and who consented for surgery were included in the study. In all patients ORIF was done under general anaesthesia. In all patients Retromandibular transmassetric approach was used to expose the fracture site and the fracture was stabilized using 3 dimensional titanium trapezoidal plates. The following parameters such as mouth opening, mandibular deviation, occlusion, surgical accessibility, reduction of fracture, adaptability of plate, nerve weakness, wound infection, postoperative haematoma and scar were assessed.

Statistical analysis: SPSS version 16

## RESULTS:

In all the patients there was improvement in mouth opening and occlusion in the immediate postoperative period obviating the need for IMF. The accessibility to the surgical site ranged from good to excellent. The reduction of fractured fragments were excellent in 60 % of patients and good in 40 %.In one patient there was transient weakness of marginal mandibular nerve which recovered by 3months postoperatively and one patient had wound infection which subsided within the first postoperative week. None of the patients had osteosynthesis device failure during the 6 months follow up period.

## CONCLUSION

Trapezoidal condylar plates [3D] are effective in treating subcondylar fractures of mandible both in terms of surgical accessibility and stability.



## KEY WORDS

3D plates, subcondylar fractures, occlusal derangement, reduction of fracture.

# ABBREVIATIONS

| | | |
|---|---|---|
| **ANOVA** | - | Analysis of variance |
| **ECG** | - | Electrocardiogram |
| **CBC** | - | Complete blood count |
| **RFT** | - | Renal function test |
| **LFT** | - | Liver function test |
| **CT** | - | Computed tomography |
| **ZMC** | - | Zygomatico maxillary complex |
| **OPG** | - | Orthopantomogram |
| **ORIF** | - | Open Reduction and Internal Fixation |
| **VAS** | - | Visual analog scale |
| **TMJ** | - | Temporomandibular joint |
| **TCP** | - | Trapezoidal condylar plates |
| **3D** | - | 3 dimensional |

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Trauma to face causes injuries to skeletal components, soft tissue and dentition as well. The incidence and pattern of fractures varies in different regions depending on geographical, cultural, environmental and social attribute [1]. Road traffic accidents is the major cause of maxillofacial trauma in developed nations, however inter personnel violence is the case in developing countries and western world.[2]

Mandible due to its prominent position is often involved in maxillofacial trauma, contributing to about 65-70 % [3]. Condylar fractures were reported as rare event comprising less than 10% of mandibular fractures before World War I. Later, **Haug & Assael [4]** reported an incidence of 30.3% for condylar fractures. Treatment of condylar fractures in maxillofacial trauma is an ongoing controversy.

As in literature, three main treatments are advocated for adult condylar fractures:

1. Closed reduction with Maxillomandibular fixation [MMF] followed by functional rehabilitation
2. Functional therapy without MMF
3. Open reduction with / without maxillomandibular fixation [MMF].

   Any injury of the condyle deserves special consideration owing to its complex anatomy, biomechanical behavior and healing potential.

According to recent concepts, fractures with a **deviation of more than 10◦, or a shortening of the ascending ramus of more than 2 mm** should be treated with open reduction and fixation, regardless of the level of the fracture[5].

It raises a problem of finding a fixation device which is able to resist local strains, adapting to anatomical and functional peculiarities of the region and also providing easy surgical access while being cost effective to the patient.

Condyle is a complex, anisotropic and viscoelastic material subjected to different types of strain on loading [tension, compression, bending or shearing]. Also a miniature osteosynthesis device becomes essential for stabilization of subcondylar fractures because of usually small size of condylar fragments. It is also mandatory to place these plates along "**Ideal line of osteosynthesis ''** for dictating predictable outcome. **Champy at al 1976** [6] experimentally located these strain lines in the mandibular body, symphysis and angle region. Later **Meyer et al**[7] proposed ideal lines of osteosynthesis in condylar region.

FIG -1 : Lines of osteosynthesis in condyle

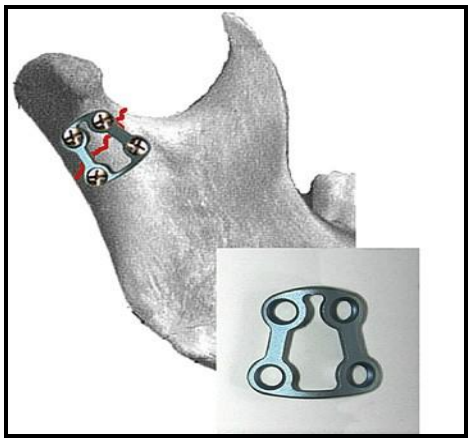


Fig 2- Trapezoidal condylar plates [3D plates]

The widely accepted technique for osteosynthesis of subcondylar fractures were double miniplate technique. But studies have documented a failure rate of **35 %** including plate fracture.

**Trapezoidal condylar plates [3D plates]** were developed to meet these biofunctional demands in the condylar region, which was first applied by **Meyer et al** for treating subcondylar fractures.

This prospective study was conducted to evaluate the effectiveness of the trapezoidal plates **[3D plates]** in open reduction and internal fixation of subcondylar fractures of mandible.

## AIM

To study open reduction and internal fixation of subcondylar fractures using 3 dimensional miniplates. The purpose of the study is to evaluate the effectiveness of three dimensional plates in open reduction and internal fixation of subcondylar fractures.

## OBJECTIVES

To evaluate the following parameters

1. Mouth opening
2. Mandibular deviation
3. Occlusion
4. Surgical accessibility
5. Reduction of fracture fragments
6. Adaptability of 3 dimensional plates
7. Per-operative time
8. Wound infection
9. Facial nerve weakness
10. Scar
11. Post-operative pain
12. Osteosynthesis device failure

**ETIOLOGY AND INCIDENCE:**

**Haug RH 1990**[8] in his epidemiological survey, studied facial fractures and concomitant injuries and reported the frequency and distribution of mandibular fractures, with condyle accounting for 21.1% of mandibular fractures.

**Ellis 1985**[9] studied 1014 condylar fractures and concluded assaults as most frequent cause accounting for 42% , falls 25.9 %, car accidents 10.9%, motorcycle accidents 5.6 %and sports related injuries 4.8% .

**Rowe and Williams 1994**[10] The mandible plays a vital role, being responsible for continuity of lower third and also entire skeleton by interacting with maxilla by occlusion and with skull base through temporomandibular joint. Special considerations should be given to condylar injuries due their anatomic peculiarities, functional complexity and healing potential.

**Booth PW 1999**[11] Fractures of mandibular condyle is one of the most common fractures of maxillofacial region accounting for more than 25-50 % of all mandibular fractures.

**CLASSIFICATION:**

Various systems of classification have been developed and put forward.

**Wassmund 1927**[12] distinguished fractures of condylar neck and condylar head. Condylar neck fractures are divided into three subgroups;

1. Vertical condylar neck fractures caused by shearing forces
2. Transverse condylar neck fractures caused by bending forces
3. Oblique condylar neck fractures by both.

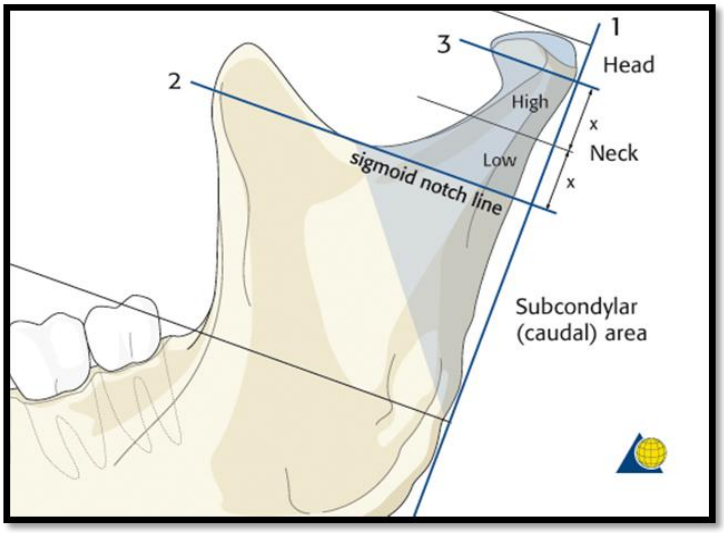



Fig 3: AO Foundation

**Wassmund 1934**[13] divided dislocated fractures into 3 types:

1. Type I – condylar neck fracture with subluxation, 10 º and 40 º angulation of condylar head and contact fragments
2. Type II- 50º-90ºangulation with slight bony contact between fragments
3. Type III severe medial displacement with no contact between fragments.

**MacLennan1952**[14] divided condylar fractures into three groups:

1. Low condylar neck fractures – the fracture line starts at sigmoid notch and extends caudally and obliquely to posterior border of mandibular ramus
2. High condylar fractures – fracture line occurs above sigmoid notch and involves condylar neck
3. Subcondylar fractures- posterior oblique fracture of mandibular ramus
4. Complete luxation – avulsion of condylar process.

**Rowe and Killey 1955**[15] classified condylar fractures into 3 groups

1. Intracapsular fractures
2. Extracapsular fractures
3. Fractures associated with lesions of capsule, ligaments, disc and surrounding bones of TMJ.

**Spiessl and Schroll 1972**[16]

It is one of the most commonly used classifications. They differentiated fractures of condylar neck and base and also considered degree of deviation, displacement and dislocation

1. Type I – condylar neck fracture without deviation or displacement
2. Type II- low condylar fracture with deviation or displacement
3. Type III- high condylar fracture with deviation or displacement with 4 sub types

   Type III a – ventral

   Type III b – medial

   Type IIIc – lateral

   Type III d- dorsal
4. Type IV - Low condylar neck fractures with dislocation
5. Type V – High condylar neck fractures with dislocation
6. Type VI- Intracapsular fracture of condylar head.

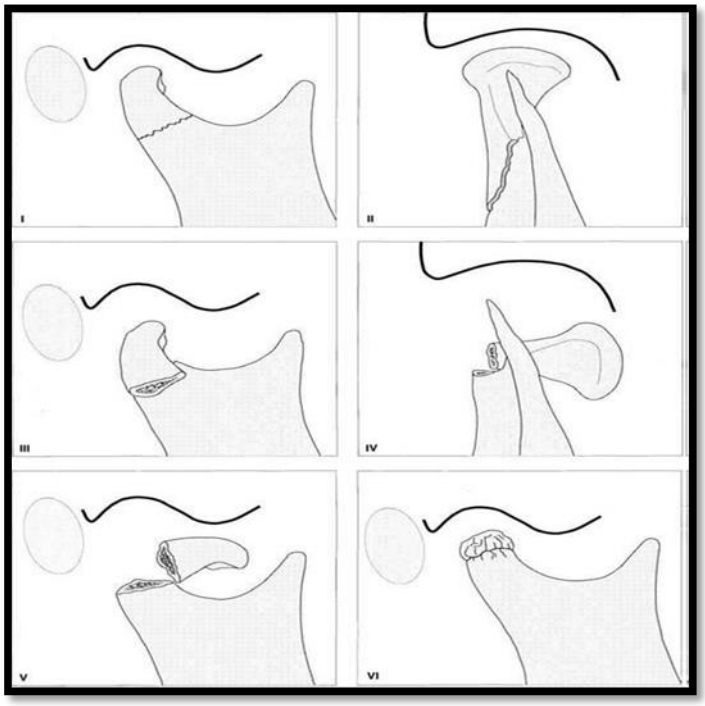



Fig 4: Spiessl and Schroll

**Loukota et al 2005**[17] proposed a sub classification of condylar process fractures which has been adopted by Strasbourg Osteosynthesis Research Group **(SORG).** He defined a **LINE A**, which is a perpendicular line extending through sigmoid notch to the tangent of ramus to improve the reproducibility of measurements.

1. Diacapitular fractures
2. Condylar neck fractures
3. Condylar base fractures.

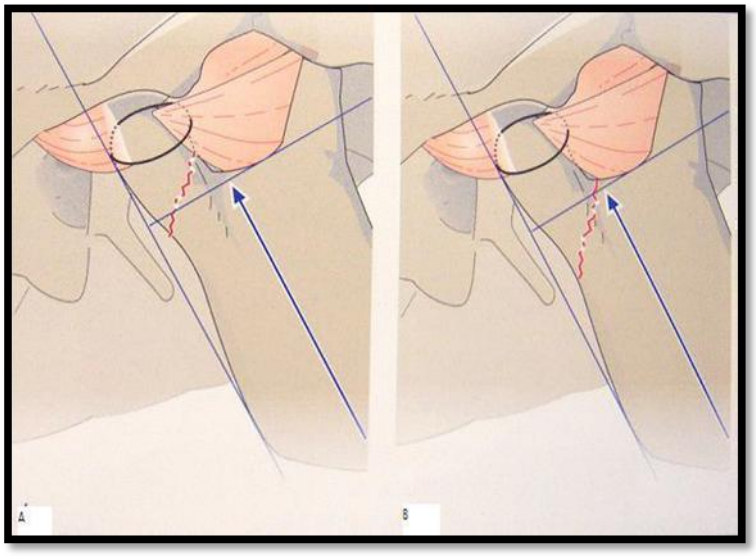


Fig 5: Sub classification of fractures of the condylar process of the mandible according to Loukota et al "Book of Fractures of the Mandibular Condyle, page 38"

**HISTORY OF TREATMENT CONCEPTS:**

The main therapeutic aims of condylar fracture are

- Restoration of mandibular shape and function
- Prevention of acute and chronic pain
- Prevention of ankylosis

**Edwin Smith Papyrus 1650**[18] evidenced the historical reference to mandibular fracture to 1650 BC. Recommendations for medical treatment of temporo-mandibular joint fractures [conservative treatment with immobilization using a chin cap and a leather cuff], were cited in the Edwin Smith's papyrus.

**Salicetti 1275** was first to advocate maxillomandibular fixation for treatment of mandibular fractures. Despite of being the fundamental concept in the management of facial fractures, Salicetti's concept disappeared for centuries until in **1887, Gilmer**[19] gave a detailed description of technique and its clinical utility.

**Desault P.J, 1805** developed a description of the diagnosis and conservative therapy of condylar fractures.

**Perthes 1924**[20] performed the first condylar surgery followed by **Wassmund 1927** performed the first Osteosynthesis of condyle using plates.

Until 1950, closed reduction was the method of choice for treating even severely displaced condylar fractures followed by early functional rehabilitation. Wire osteosynthesis mandated 6 weeks immobilization, to prevent re-dislocation but this led to scars around temporomandibular joint leading to restricted function.

**Newman 1998**[21] concluded that 'if either condyle is dislocated or displaced, ORIF of at least one condyle is a treatment choice'. In their study, only nine patients with 10 fractures underwent ORIF and the other 52 patients underwent closed treatment. The functional outcomes, TMJ disturbance and complications were not evaluated completely.

**Brandt MT, Haug RH 2003**[22] concluded that Open reduction and internal fixation (ORIF) was found to provide better functional reconstruction of mandibular condylar fractures as compared to closed reduction (CR) and Maxillomandibular fixation.

**INDICATIONS FOR OPEN REDUCTION OF CONDYLE FRACTURES**

**Zide and Kent 1983**[23] proposed the **absolute indications for open reduction** as:

- Displacement into the middle cranial fossa,
- Impossibility of obtaining adequate occlusion by closed reduction,
- Lateral extracapsular displacement of the condyle, and

- Invasion by a foreign body (e.g., gunshot wound).

These indications pertain to children as well as to adults.

**Relative indications for open reduction**

- Bilateral condylar fractures in an edentulous patient when a splint is unavailable or when splinting is impossible because of alveolar ridge atrophy.
- Unilateral or bilateral condylar fractures when splinting is not recommended for medical reasons or where adequate physiotherapy is impossible (patients with seizure disorders, psychiatric problems, alcoholism, refractory behavior, or mental retardation or retardation secondary to neurologic injury)
- Bilateral condylar fractures associated with comminuted midfacial fractures
- Bilateral condylar fractures and associated gnathologic problems

**Ellis, Throckmorton et al. 2000; Villarreal, Monje et al. 2000**[24, 25]

The therapeutic choice must be selected based on very important physical and imaging evidence and requirements such as: level of the fracture, loss of ramus height, unilateral or bilateral fractures, occlusal state including completeness of the dentition, the dental malocclusion and mandibular dysfunction, degree and direction of displacement or dislocation, presence of concomitant maxillofacial fractures, complexity of surgical approach, risk of hypertrophic and/ or keloid scarring, the clinical experience of the surgeon, patient's age, general state, and willingness to be operated, and possibility of providing physical therapy.

**Hans Henning- Horch (Hrsg) 2007** [26]

He proposed the **absolute indications** for the use of an open technique in subcondylar fractures

- High grade of dislocation (loss of condyle–disc–fossa-relation).
- Significant displacement (> 30° and/or vertical – loss > 4 mm **[Joos and Kleinheinz 1998**][27]or 5 - 6 mm [**Eckelt 2000]**[28]**.**
- Considerable diastases of the fracture plane and intervening of soft tissue, which lead to non-union or pseudarthrosis.
- Inability to achieve adequate occlusion by conservative therapy **[Joos and Kleinheinz 1998**][27].

**Relative indications of surgical treatment of subcondylar fracture in adults**

When associated with comminuted midface fracture, so that the vertical support by mandibular joint is not ensured **[Eckelt 2000**[28]**; Neff, Kolk et al. 2005]**[29]**.**

- Medical indications prohibiting intermaxillary fixation [**Joos and Kleinheinz 1998**][27].
- Bilateral fractures in edentulous jaw [**Joos and Kleinheinz 1998**][27]**.**
- Displaced condyle with edentulous or partially edentulous mandible with posterior bite collapse [**Valiati, Ibrahim et al 2008]**[30]**.**
- Multiple fractures in the mandible [**Horch and Herzog, 1992]**[31]**.**

**Schneider, Erasmus et al. 2008**[32] proposed the fractures with a deviation of more than **10◦,** or a shortening of the ascending ramus of **more than 2 mm** should be treated with open reduction and fixation, regardless of the level of the fracture.

**Martin and Lee 2003**[33] approached condyle via endoscopic assisted intraoral approach and concluded that open reduction can be done when there is loss of chin projection, and asymmetry at rest and/or in function.

**Choi et al 2003**[34] After analyzing the computed tomographic findings, he documented that no sclerosis or erosion of fractured condyles after ORIF and reported that anatomically reducing fractured condyles might avoid adverse postoperative joint changes. His results were consistent with the other authors who used ORIF for bilateral condylar fractures.

**Schneider M et al 2008**[32] conducted a randomized, prospective, multicenter study with special evaluation of fracture level and concluded that with recent advances and surgical facilities available, fractures with a deviation of more than 10◦, or a shortening of the ascending ramus of more than 2 mm, irrespective of level of the fracture should be treated with open reduction and fixation.

**Sawazaki, Lima Junior et al. 2010**[35] advocated open reduction whenever enough room is available for plate and screw fixation.

## OSTEOSYNTHESIS OF CONDYLE FRACTURES

The earliest reports of mandibular fractures treated with an open reduction were from **Buck**[36] using an iron loop, and **Kinlock**, using a silver wire. **Gilmer**[19] **in 1881** described the use of two heavy rods placed on either side of the fracture that were wired together. **Schede (circa 1888)** is credited with the first use of a true bone plate made of steel and secured with four screws. In the **1960s, Luhr**[38] developed the vitallium mandibular compression plate through his research on rigid fixation of the facial skeleton.

**Pape et al 1980**[38] were the first to use miniplates for treating fractures of the mandibular condyle. The plates were fixed using a screwdriver applied transbuccally. In 21 out of 24 osteosynthesis of low fractures of the condylar neck, postoperative function was satisfactory. However, in 12 patients it was not possible to restore the condylar position with regard to the condylar axis [**Horch et al., 1983].**

**Meyer c et al 2000**[39] Functional loads in the condylar region results in compression along the posterior border and tension along the anterior border of the ramus and the zone below the sigmoid notch.

**Meyer C, Kahn JL, Boutemi P 2002**[40] analyzed the photo elastic deformation of bone in the region of mandibular condyle during mastication and concluded that the Osteosynthesis must stabilize both anterior and posterior border allowing early function and minimum stress concentration.

**Hammer B, Schier P, Prein J 1977**[41] studied osteosynthesis of condylar neck factures in 30 patients and concluded that single 2.4mm plate or 2mm mini dynamic compression plate can be used for fixation of condylar neck fractures as they resist rotation and three point bending.

**Asprino L, Consani S, de Moraes M 2006**[42] conducted a biomechanical study to compare the different plating techniques for treating subcondylar fractures and concluded that two plating system [a miniplate parallel to condylar axis and second miniplate parallel to mandibular notch ]for subcondylar fracture resisted the functional load better . It is advocated to place minimum of two screws per

fractured fragment for better stability and outcome. But the condyle region is narrow and not always possible to place bulky osteosynthesis devices, due to limited availability of bone for placement of screws. To overcome these, various plate designs were put forward in recent years in such a way that the plates occupy less space while maintaining the stress distribution along the zones of tension and compression.

**Meyer C, Martin E, Kahn JL, Zink S 2007**[43] used single L**,** Y and 3 D plates in treating the condylar fractures for analyzing the stress concentration in condyle region during functional loading.

**Rallis, Mourouzis et al. 2003 Rallis**[44] et al reported the cost of additional plate and longer operation time as disadvantage of the two plating concept.

**Eckelt and Gerber 1981**[45] proposed that axial anchor lag screws are an alternative to plate fixation of condylar fractures. It is a type of osteosynthesis in which absolute interfragmental functional compression is produced by screws that transfix the fracture gap with the possibility for easy removal of the element without re-exposure of the TMJ area. This method was modified by Eckelt and Graber 1981, which includes a set of lag screws of different diameters and lengths.

**Farmand M 1995**[46] developed **Titanium 3 D plating system** to meet the requirements of semirigid fixation with lesser complications. The word 3D is a misnomer as the plate is not three dimensional but resist the forces in three directions namely bending, shearing and torsion . The basic concept of 3-D fixation is that a geometrically closed quadrangular plate secured with bone

screws creates stability in three dimensions. The stability is gained over a defined surface area and is achieved by its configuration and not by thickness or length, and also the large free areas between the plate arms and minimal dissection permit good blood supply to the bone.

**Lauer et al 2006**[47] conducted a study on transoral osteosynthesis of condyle using 3 D delta plates. The 3-D Modus Delta-Plate (Medartis, Basel, Switzerland) is a 4-hole delta-shaped miniplate, the base of the delta is 12mm and fixed on the ramus and its upper arm is 5mm is fixed on the condylar fragment and has a length of 20mm and thickness of 1 mm. A recently published study reports rather good clinical results, but a 15.4% radiological failure rate (secondary displacement of the fracture and/or screw loosening).

**Meyer, C., L. Serhir, et al 2006**[48] did experimental evaluation of three osteosynthesis devices used for stabilizing condylar fractures of the mandible and concluded that trapezoidal condylar plates are developed to meet the biofunctional demand in the condylar region. They are trapezoidal in shape so that the anterior arm of the plate lies precisely along the tension lines under the sigmoid notch and the posterior arm along the axis of condylar neck. The Trapezoidal condylar plates come in different sizes to fit high to low condylar fractures and anatomic variations.

**Meyer, C., S. Zink, et al 2008**[49] applied trapezoidal condylar plate [3D plate] technique in ORIF of subcondylar fractures for over a period of 3.5 years and evaluated the clinical and radiographic results with minimum 6 months follow up per patient involving 64 patients. It showed a mean duration of the surgical

procedure to be 30 minutes per fracture and all fractures were stabilized using one trapezoidal condylar plate. No reports of plate fracture. All fractures appeared to be consolidated at 6 month recall. 83 % of cases showed immediate postoperative reduction. In 6.6% secondary displacement was reported.

At the end of 6 months 79 % of fractures showed anatomic reduction radiographically and occlusion was fully restored in 94 % of patients. Mandibular movements were symmetrical in 95 % of cases and none of the patients had mouth opening less than 40 mm. No temporomandibular joint problems were reported and with no evidence of pain or noise in the joint during function. 98 % of the patients were satisfied with scar appearance. No evidence of transient or permanent facial nerve dysfunction. Only one plate had been reported to be removed during ninth post operative month considering the young age of the patient in order to avoid any interference in growth.

**Suzuki, T., H. Kawamura, et al 2004**[50] Resorbable osteosynthesis are particularly valuable in high condylar fractures for preventing osteoarthrosis resulting from chronic tissue irritation and long term mechanical irritation with local metallosis. They appear to yield satisfactory results in terms of stability and handling. Screws longer than 8mm are necessary to achieve stable fixation in class VI fractures. Based on the data available so far an uncomplicated clinical course can be expected in majority of cases.

**Surgical approaches to the fractured Mandibular Condyle**

Many approaches to the TMJ have been developed

- Preauricular
- Retroauricular
- Temporoauricular
- Retromandibular
- Submandibular
- Intraoral

Each approach has its own advantages, disadvantages and complications.

**Bos, R. R., R. P. Ward Booth, et al 1999**[51] documented that though several attempts have been made to reach a common idea in choosing the surgical approach, no consensus exists on the surgical techniques for condylar fracture treatment.

**Schneider, Lauer et al. 2007**[52] They compared the long-term results following different approaches using functional, axiographical and radiological findings and concluded that the approach to be used depends on various factors such as anatomical location of the fracture, degree of displacement, other associated mandibular fractures, the type of osteosynthesis to be used.

**Biglioli and Colletti 2008**[53] Different surgeons prefer different approaches according to their experience with the technique and their personal beliefs.

**Eckelt et al 2000**[54]

Ideally, the following criteria should be considered in selecting appropriate approach;

- It should allow maximum visibility of the fracture region.
- It should enable and facilitate a secure repositioning of the fragments.
- It should avoid damage to the parotid gland, branches of the facial nerve, to major vessels (e.g., internal maxillary artery, retromandibular vein).
- It should maximize the cosmetic wound closure and, if possible leave no visible scar.

**Hinds et al 1967**[55] documented that retromandibular approach as the best approach for subcondylar fractures. This incision is best placed in a skin fold with 4 to 5 cm length, the line begins 1cm below the lobe of ear and 1cm posterior to ramus of mandible. Parotid gland is retracted anteriorly and masseter muscle is separated to reach fracture gap.

**Ellis, McFadden et al. 2000; Manisali, Amin et al. 2003**[56] reported an incidence of 19.3-30 % of facial nerve damage when retromandibular approach is used.

**Tang, Gao et al 2009**[57] **The** facial nerve injury is a result of a retraction of the parotid gland from its posterior or inferior lobe to expose the fracture site and consequently facial nerve compression can be caused by the retractor during surgery.

**Girotto Mancini et al 2011**[58] reported that retromandibular incision is a safe approach, and it takes little time to perform the operation. Moreover, the distance

to the fracture site is short, and compared to the Risdon's approach and it allows a closer view of the mandibular ramus and condylar process.

**Schneider, Lauer et al. 2007**[52] proposed retromandibular approach as the most appropriate method when dealing with fractures of the base of the condyle and condylar neck.

**COMPLICATIONS**

**Ebenezer V, Ramalingam B et al 2011**[59]**, Kim et al 2012**[60] They have documented an incidence of 20 % and 17 % of salivary fistula in their study.

**Downie JJ, Devlin MF, Carton AT, et al 2009** [61] Temporary or permanent paresis of branches of the facial nerve, wound infection, transient salivary fistula, failure of osteosynthesis, pseudo arthrosis, functional occlusal disturbance or malocclusion, and the need for revisional surgery.

**Worsaae and Thorn 1994**[62] found most of the scars are almost invisible after submandibular approaches to the condylar process.

**Chossegros et al 1996**[63] reported one widened scar out of 19 cases after using retromandibular approach.

**Tasanen and Lamberg et al 1976**[64] reported that 15 of 27 patients had excellent wound healing and 10 had good healing; 2 cases developed keloids.

**Kallela et al 1995**[65] documented that 1 of 11 patients who were treated by a submandibular approach complained about the scar.

**Pereira et al 1995**[66] reported a good quality scar in all cases when the preauricular approach was used.

**Yamamoto et al 2013**[67] He concluded that **facial** nerve dysfunction during open reduction of condylar fractures may be due manipulation of fractured fragments, tissue dissection, excessive retraction, placement of osteosynthesis devices. The buccal branch of the facial nerve was the most commonly affected their series (9/18; 50%). Similar outcomes were reported in the studies of **Hyde et al. 2002**[68]**; Vesnaver et al. 2005**[69]**.**

**ANATOMICAL REVIEW OF THE TEMPOROMANDIBULAR JOINT**

The TMJs are diarthrodial ginglymoid, freely movable and synovial articulations of the bicondylar type.

The term "diarthrodial" is used because the joint has two articulating bone components,

- the mandibular condyle inferiorly, and
- the articular eminence and glenoid-fossa of the temporal bone superiorly **[Fonsica, Raymond J.2000]**[70]

The temporal surface combines the mandibular fossa and the articular tubercle, the roof of the fossa is thin and separates the brain from the joint cavity, therefore during surgical manipulation at the fossa, care should be taken to avoid perforating the roof of the fossa.

The muscles of mastication associated with the TMJ include

- Temporalis,
- Masseter,
- Lateral pterygoid, and
- Medial pterygoid.

Temporalis, deep masseter, and superior belly of the lateral pterygoid have been observed within portions of the articular disk anteriorly, while the inferior belly of lateral pterygoid inserts onto the medial aspect of the condylar neck. Owing to this unopposed muscle pull, fractures of the subcondylar fractures often exhibit anterosuperior rotation.

Low subcondylar fractures may have variable muscle pull from the medial pterygoid muscle and the masseter depending upon fracture configuration. **[Blasberg B, Greenberg MS,2003].**

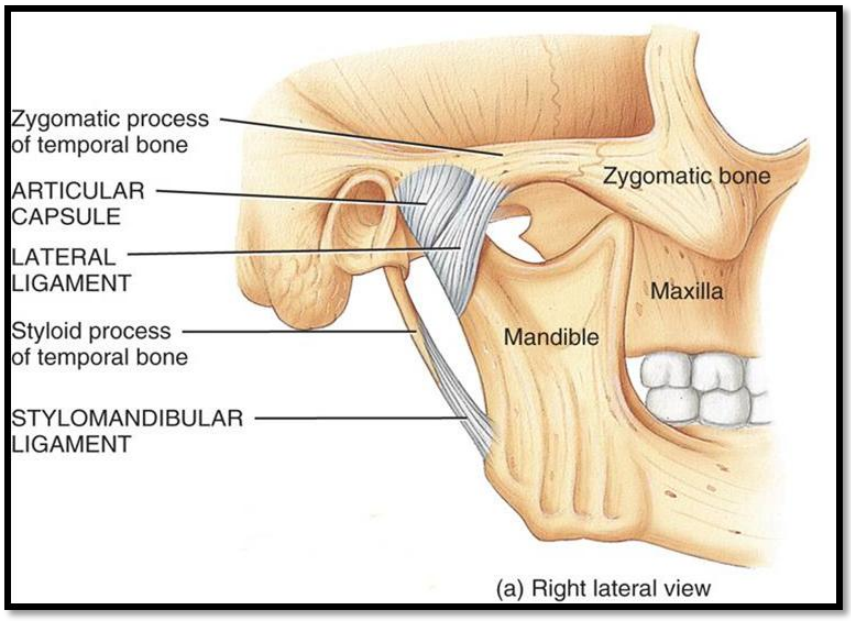



Fig 5: Ligaments of TMJ

Accessory Muscles includes

- Digastric,
- Mylohyoid,
- Geniohyoid,
- Buccinators,
- Cervical muscles Sternocleidomastoid, Splenius capitis and Trapezius **[Blasberg B, Greenberg MS, 2003].**

**THE MANDIBULAR CONDYLE**

The condyle lies in the articular fossa, with its axis is perpendicular to the mandibular ramus. It is connected by a thin collum, with the ramus forming an angle of **25°** with the frontal plane.

The condyle has two poles,

a. Lateral pole b. Medial pole

to which the disc is fixed by strong fraenula.

Anatomically, the adult condyle is composed of dense cortical bone and variable amount of cancellous bone depending upon the age of the patient.

**THE AVERAGE MEASUREMENTS OF CONDYLE ARE:**

**Head:**

- **Sagittal - 8.5 mm**
- **Transverse- 21mm**

**Collum** :

- **Sagittal - 22 mm**
- **Transverse - 5mm at its neck.**

  This configuration results in a preponderance of subcondylar fractures in adults rather than fractures of the condylar head **[Jean-luc Kahn. 2009].**

**THE DISC AND ITS ATTACHMENTS**

The articular disk is an oval plate of fibro cartilage that is attached circumferentially to the capsule and interposed between the temporal and mandibular surfaces, interlocking with the condyle during movement by powerful

lateral and medial fraenula. The posterior ridge is prolonged by the "bilaminar zone".

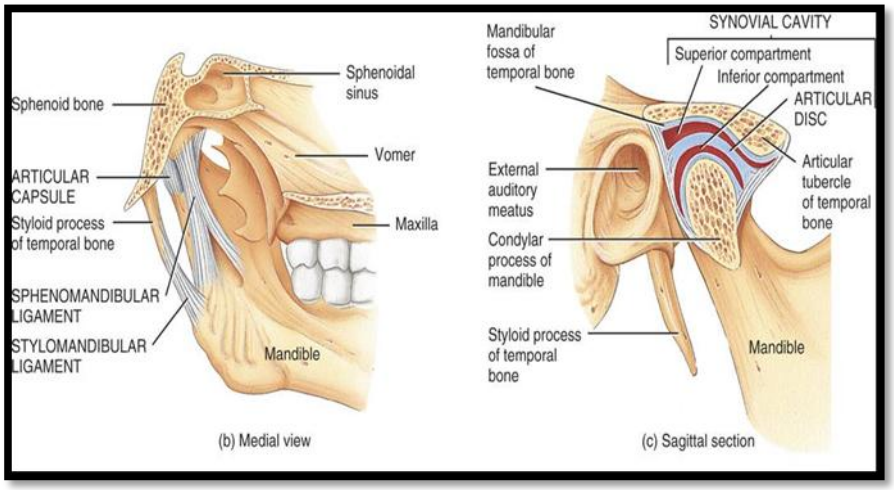
The **bilaminar zone** is a vascular, innervated tissue that plays an important role in allowing the condyle to move forward. The anterior ridge, closely connected to the superior bundle of the lateral pterygoid muscle, separates the tempromandibular articulation into two compartments:

- **The upper disco-temporal compartment - translation.**
- **The lower disco-mandibular compartment - rotation** [**Richard S. Snell, 2007**]

**CAPSULE**

The joint capsule is a fibroelastic, highly vascular, and highly innervated dense connective tissue

- The lateral aspect of the capsule attaches to the zygomatic tubercle, the lateral rim of glenoid fossa, and the postglenoid tubercle.
- The spine of sphenoid, the sphenomandibular ligament, and the middle meningeal artery are closely related to the middle surface.



The surgeon has to be aware of these relationships and should avoid interfering with the medial capsule. The disc together with its muscle attachments forms "**disc – capsule-muscle – complex''.** Inferiorly, the capsule attaches to the periosteum of the neck of the condyle. Lateral retraction of the capsule should allow access to the upper joint space. Incising and reflecting the capsule usually lead to the cutting of the nerve fibers, which may result in a period of postoperative analgesia and relief from pain [**Fonsica, Raymond J. 2000]**[70].

**VESSELS AND NERVES OF THE TMJ**

- Branches of superficial temporal artery,
- Branches of maxillary artery
- Branches of facial artery.

The satellite veins pass into the **external jugular vein**.

The nerves arise from the **mandibular nerve V3 CN** [**Jean-luc Kahn. 2009].**

**BIOMECHANICS OF CONDYLAR FRACTURE:**

In spite of the fact that the temporomandibular joint is well protected in the glenoid fossa, and that the condylar process is relatively well protected by the zygomatic arch against direct injury, TMJ injuries are relatively common.

In terms of strength, the condylar neck constitutes the **weakest region of the entire mandible** and is therefore the most susceptible to fracture as a result of indirect forces, where the forces of impact are transmitted along the mandible from distant sites such as the angle, body or symphysis to the condylar neck [**Dimitroulis 1997]**[71]**.**

The central force in the middle of chin (e.g. bicycle accident) can cause a bilateral condylar fracture. In this case, the fracture is called **bending-fracture**, which is caused by the clash of condyle against the posterior rim of the glenoid fossa.

If the force is applied to the lateral aspect of the mandible at the level of canine and premolar region, not only there be a fracture of the mandible on the side of the force, but tension will develop along the contra lateral condylar neck leading to fracture in this area **[Peterson LJ 1992, book].**

But if the force applied is not exhausted in the resulting fracture, a dislocation fracture will occur, in this case, the potential remaining force leads to a rupture of the periosteum at the fracture site, and thus a shift of the fragments is an expected result because of the muscle tension at the fracture site **[Austermann K .H. et al. 1980][72].**

**BASIC PRINCIPLES OF MANDIBULAR OSTEOSYNTHESIS**

- Rigid osteosynthesis - **AO principles**
- Functionally stable osteosynthesis – **Champy et al 1976[6]**

  Based on the theory of neutralization of tension forces that physiologically occurs in "ideal lines of osteosynthesis" [**Michelet, Deymes et al. 1973**][73], Champy experimentally located these strain lines in the mandibular body, symphysis and angle region.

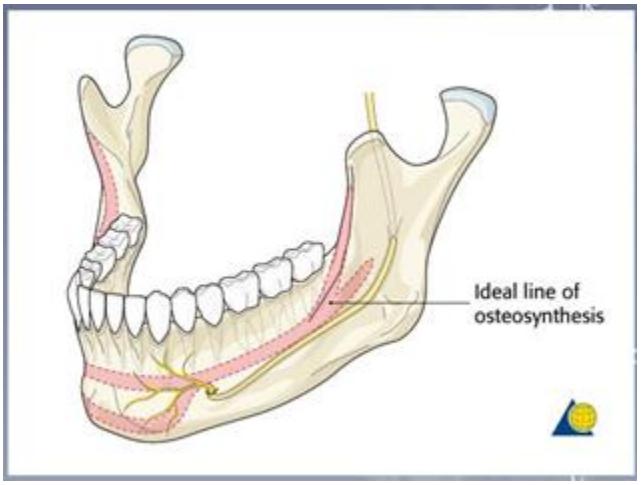



Fig 6: Ideal line of Osteosynthesis

Later **Meyer et al** [7] proposed ideal lines of osteosynthesis in condylar region. The upper and the anterior line is located over the tension strain lines occurring under the mandibular notch during mastication. It is used for placement of the tension plate according to functionally stable osteosynthesis principles. The lower and the posterior line located over the compression strain lines and used only for placement of neutralization plate.

## MATERIALS AND METHODOLOGY

This study was conducted on five patients reporting at the Department Of Oral And Maxillofacial Surgery, Tamil Nadu Government Dental College and Hospital. The subjects were patients who sustained condylar fractures associated with or without other facial fractsures.

## METHODOLOGY

A written informed consent was obtained from the patients. Procedure to be performed was explained to the patient with a detailed history followed by a thorough clinical examination. CT scan in all three planes with 3D reconstruction was taken and findings were recorded in a specially prepared case history Performa.

Preoperatively, the degree of displacement was measured using OPG. Postoperatively, the patients were followed up for 6 months to assess the mouth opening, occlusion, mandibular deviation, facial nerve paralysis and scar status.

## INCLUSION CRITERIA:

- Unilateral / bilateral subcondylar fractures
- Simple and compound fractures
- Associated with other mandibular fractures/facial fractures
- Subcondylar fractures with deranged occlusion
- Patients between 15-40 years of age group
- Dentulous patients

**EXCLUSION CRITERIA:**

- High condylar fractures
- Comminuted condylar fractures
- Pediatric condylar fractures
- Patients with systemic disorders and immuno compromised patients
- Edentulous patients
- Pathologic fractures
- Patients not willing for surgery

**PRE-OPERATIVE ASSESSMENT**

A detailed history was obtained from all the patients, clinical examination including general examination was done, radiographs, CT scan and facial photographs were taken.

**CLINICAL EXAMINATION**

Both extra oral and intraoral examinations were done to assess the injury and make a diagnosis.

**INVESTIGATIONS**

All the patients were advised OPG, CT scans in all the three planes with 3D reconstruction. All routine investigations were done which included bleeding time, clotting time, hemoglobin level, RBC count, total and differential WBC count, platelet count, ESR, PC, RFT, blood grouping, ECG, Chest x ray and HIV.

**ARMAMENTARIUM**

1. Mouth mirror
2. Sickle probe
3. Bard Parker handle with 15 blade
4. Skin hook
5. Molt's periosteal elevator
6. Howarth
7. Kilner retractor
8. Toothed forceps
9. Non toothed forceps
10. Mayo scissors
11. Tenotomy scissors
12. Condylar retractor
13. Screw holder and driver
14. Needle holder
15. Suture cutting scissors
16. Towel clips
17. Wire cutter and twister
18. Suction tip
19. Mouth prop
20. 26 Gauge wire
21. Suture material
22. Saline cup

**TRAPEZOIDAL 3 D PLATES AND SCREWS**

After ruling out head and cervical spine injury, selected cases were planned for open reduction and internal fixation based upon their clinical and radiographic assessment.

All patients were treated under General anesthesia. After oral prophylaxis, Erich's arch bars were placed and occlusion was achieved through MMF whenever possible. Fracture site was exposed via Retromandibular approach. General anesthesia induced and maintained through Naso endo tracheal intubation.

**Step 1. Preparation and Draping**

Pertinent landmarks of the face such as the corner of the mouth, lower lip, and the entire ear were left uncovered during the procedure. These landmarks orient the surgeon to the course of the facial nerve and allow observation of lip motor function.

**Step 2. Marking the Incision and Vasoconstriction**

The skin was marked prior to the injection of a vasoconstrictor. The incision for the retromandibular approach begins 0.5 cm below the earlobe and continues inferiorly for 5cm. It was placed just behind the posterior border of the mandible and may or may not extend below the level of the mandibular angle, depending on the extent of exposure desired. Epinephrine (1:200,000) without a local anesthetic was injected deeply, to aid in homeostasis at the time of incision.

**3. Skin Incision**

The initial incision was carried through skin and subcutaneous tissues to the level of the platysma muscle present in that area.

**Step 4. Dissection to the Pterygomasseteric Muscular Sling**

After retraction of the skin edges, the platysma muscle overlying the superficial musculo aponeurotic system (SMAS) became visible. A scalpel was used to incise through the fusion of platysma muscle and SMAS in the vertical plane. A hemostat was spread open parallel to the anticipated direction of the facial nerve branches. The marginal mandibular branch of the facial nerve was often, but not always, encountered during this dissection and preserved.

**Step 5. Division of the Pterygomasseteric Sling and Submasseteric Dissection**

After retraction of the dissected tissues anteriorly (with the marginal mandibular branch of the facial nerve under the retractor), a broad retractor was placed behind the posterior border of the mandible to retract the retromandibular tissues medially. The posterior border of the mandible with the overlying pterygomasseteric sling was seen.

The pterygomasseteric sling was incised sharply with a scalpel. The sharp end of a periosteal elevator was drawn along the length of the incision to strip the tissues from the posterior border of the ramus. The masseter was stripped from the lateral surface of the mandible using periosteal elevators.

The entire lateral surface of the mandibular ramus, up to the level of the temporomandibular joint capsule as well as the coronoid process, was exposed. Retraction of the masseter muscle was facilitated by inserting a suitable retractor into the sigmoid notch

When using this approach for open treatment of condylar process fractures, it was often necessary to distract the mandibular ramus inferiorly. A

simple technique was followed by first applying a bicortical bone screw through the gonial angle region, taking care to avoid the inferior alveolar canal and using 24 gauge wire to retract the mandible inferiorly allowing in reduction of fracture fragments.

Once the fracture was reduced, the 3 D plate was positioned such that long arm of the plate was along the posterior border. 2x6 mm screws were used, two on each side of the fractured segment and the screw over the proximal fragment was placed first. After checking for occlusion and ensuring the correct position of condyle in the fossa the surgical wound was irrigated with saline and betadine. Any associated mandibular fracture, was opened intraorally and appropriate miniplates were used for osteosynthesis as per **Champys principles.**

**Step 6. Closure**

Layer wise closure carried out with 3-0 vicryl and 3-0 prolene . Care was taken to close the dissected pterygomassteric sling. Pressure dressing placed.

**POST OPERATIVE CARE**

The patients were administered post-operative medications which included intravenous antibiotics, anti-inflammatory analgesics for a period of about 7 days to 10 days, maintaining adequate hydration status and nutritional requirements. A soft diet and physiotherapy was started on the first postoperative day. Patients were not kept under postoperative IMF. Sutures were removed between the $8^{th}$ and $10^{th}$ post-operative day. All the patients were advised soft diet for about 3 weeks postoperatively and instructed to maintain good oral hygiene.

**FOLLOW UP**

All patients were followed up for 1 month, 3 months, and 6months. OPG was taken to assess the osteosynthesis. During the follow up visit, mouth opening, mandibular deviation, occlusion, pain, scar and facial nerve status were assessed.

**Marking the Incision**

**Skin Incision**

**Exposure of platysma**

**Identification and preservation of marginal mandibular nerve**

**Reduction of fracture**

**Plating**

**Closure**

## CASE REPORT-1

**Name**: Mr. BALAJI

**Age:** 29 Years

**Sex**: MALE

**Chief Complaint:** Complains of pain over lower jaw and right ear region since 2 day**s.**

**History Of Presenting Illness:** History of road traffic accident 2 days back

**Past Medical/ Surgical History**: Not relevant

**General Examination:** Patient is moderately built & nourished.

No signs of pallor, pedal edema, peripheral lymphadenopathy, cyanosis, clubbing and Icterus.

| | |
|---|---|
| Respiratory system | B/L vesicular breath sounds |
| Cardiovascular system | S1, S2 +, no murmur |
| Neurological system | No Focal neural abnormality, no evidence of cervical spine injury |
| Per abdomen | Soft |

**Local examination : Extra oral examination**

| | |
|---|---|
| Facial asymmetry | Present |
| Mouth opening | Restricted |
| Mandibular deviation | Deviation towards right |
| Step deformity | Left Parasymphysis region |
| Tenderness over preauricular region | Present |

**Intra oral Examination**

| | |
|---|---|
| Occlusion | Deranged |
| Mobility of fragments | Mobility of fractured fragments between 32 and 33 |
| Sublingual hematoma | Present |

**OPG findings** : Fractured Right subcondyle with displacement, Left parasymphysis fracture

**CT findings :** Fractured Right subcondyle with displacement, left Parasymphysis fracture

**Diagnosis** : Fractured Right subcondyle with displacement, left parasymphysis fracture of mandible.

**Classification according to Spiessl and Schroll (1972) : Type II**

**Treatment plan :** ORIF under GA

**CASE REPORT-2**

**Name**: Mr. ANAND

**Age:** male

**Sex**: 26 years

**Chief Complaint:** Complains of pain over lower jaw and left ear region since 2 day**s.**

**History Of Presenting Illness:** History of hit by cricket ball 3 days back

**Past Medical/ Surgical History**: Not relevant

**General Examination:** Patient is well built & nourished.

No signs of pallor, pedal edema, peripheral lymphadenopathy, cyanosis, clubbing and Icterus.

| | |
|---|---|
| Respiratory system | B/L vesicular breath sounds |
| Cardiovascular system | S1, S2 +, no murmur |
| Neurological system | No Focal neural abnormality, no evidence of cervical spine injury |
| Per abdomen | Soft |

**Local examination : Extra oral examination**

| | |
|---|---|
| Facial asymmetry | Present |
| Mouth opening | Restricted |
| Mandibular deviation | Deviation towards left |
| Condylar movements | Restricted on left |
| Tenderness over preauricular region | Present |
| Step deformity | Left parasymphysis region |

**Intra oral examination**

| | |
|---|---|
| Occlusion | Deranged |
| Mobility of fragments | Mobility of fractured fragments between 43 and 44 |
| Sublingual hematoma | Present |

**OPG findings** : Fractured left subcondyle with displacement, right parasymphysis fracture

**CT findings** : : Fractured left subcondyle with displacement, right parasymphysis fracture

**Diagnosis** : Fractured left subcondyle with displacement, right parasymphysis fracture of mandible.

**Classification according to Spiessl and Schroll (1972) : Type II**

**Treatment plan** : ORIF under GA

**CASE REPORT-3**

**Name**: Mr. Ragupathy

**Age :** Male

**Sex**: 28 years

**Chief Complaint:** Complains of pain over lower jaw and left ear region since 2 day**s.**

**History Of Presenting Illness:** History of self fall from bike 2 days back

**Past Medical/ Surgical History**: Not relevant

**General Examination:** Patient is well built & nourished.

No signs of pallor, pedal edema, peripheral lymphadenopathy, cyanosis, clubbing and Icterus.

| | |
|---|---|
| Respiratory system | B/L vesicular breath sounds |
| Cardiovascular system | S1, S2 +, no murmur |
| Neurological system | No Focal neural abnormality, no evidence of cervical spine injury |
| Per abdomen | Soft |

**Local examination : Extra oral examination**

| | |
|---|---|
| Facial asymmetry | Present |
| Mouth opening | Restricted |
| Mandibular deviation | Deviation towards left |
| Condylar movements | Restricted on left |
| Tenderness over preauricular region | Present |

**Intra oral examination**

| | |
|---|---|
| Occlusion | Deranged |
| Mucosa | Laceration of upper labial mucosa |

**OPG findings** : Fractured left subcondyle with displacement

**CT findings** : : Fractured left subcondyle with displacement

**Diagnosis :** Fractured left subcondyle with displacement

**Classification according to Spiessl and Schroll (1972) : Type II**

**Treatment plan** : ORIF under GA

**CASE REPORT-4**

**Name**: Mr.VELU

**Age:** Male

**Sex**: 28 years

**Chief Complaint:** Complains of pain over lower jaw and left ear region since 2 day**s.**

**History Of Presenting Illness:** History of self fall from two wheeler 4 days back

**Past Medical/ Surgical History**: Not relevant

**General Examination:** Patient is well built & nourished.

No signs of pallor, pedal edema, peripheral lymphadenopathy, cyanosis, clubbing and Icterus.

| | |
|---|---|
| Respiratory system | B/L vesicular breath sounds |
| Cardiovascular system | S1, S2 +, no murmur |
| Neurological system | No Focal neural abnormality, no evidence of cervical spine injury |
| Per abdomen | Soft |

**Local examination : Extra oral examination**

| | |
|---|---|
| Facial asymmetry | Present |
| Mouth opening | Restricted |
| Mandibular deviation | Deviation towards left |
| Condylar movements | Restricted on left |
| Tenderness over preauricular region | Present |
| Step deformity | Between 43 and 44 |

**Intraoral examination**

| | |
|---|---|
| Occlusion | Deranged |
| Mucosa | Laceration of upper labial mucosa |
| Sublingual hematoma | Present |

**OPG findings** : Fractured left subcondyle with displacement, right parasymphysis of mandible

**CT findings :** : Fractured left subcondyle with displacement, right parasymphysis of mandible

**Diagnosis :** Fractured left subcondyle with displacement, right parasymphysis of mandible

**Classification according to Spiessl and Schroll (1972) : Type II**

**Treatment plan :** ORIF under GA

**CASE REPORT-5**

**Name**: Mr.SATHISH RAJ

**Age :** 29

**Sex:** male

Complains of pain over lower jaw and left side of face since 2 day**s.**

**History Of Presenting Illness:** History of self fall from two wheeler 2 days back

**Past Medical/ Surgical History**: Not relevant

**General Examination:** Patient is well built & nourished.

No signs of pallor, pedal edema, peripheral

lymphadenopathy, cyanosis, clubbing and Icterus.

| | |
|---|---|
| Respiratory system | B/L vesicular breath sounds |
| Cardiovascular system | S1, S2 +, no murmur |
| Neurological system | No Focal neural abnormality, no evidence of cervical spine injury |
| Per abdomen | Soft |

**Local examination :Extra oral examination**

| | |
|---|---|
| Facial asymmetry | Present |
| Periorbital edema | Left side |
| Subconjuctival hemorrhage | Left eye |
| Eye movements | Not restricted |
| Diplopia/ enopthalmous | Not present |
| Mouth opening | Restricted |
| Mandibular deviation | Deviation towards left |
| Condylar movements | Restricted on left |
| Tenderness over preauricular region | Present |
| Step deformity | Between 43 and 44 |

**Intraoral examination**

| | |
|---|---|
| Occlusion | Deranged |
| Mucosa | Laceration of upper labial mucosa |
| Sublingual hematoma | Present |
| Mobility of fragments | Between 43 and 44 |

**OPG findings** : Fractured left subcondyle with displacement, right parasymphysis of mandible, left zygomatic arch

**CT findings :** : Fractured left subcondyle with displacement, right parasymphysis of mandible

**Diagnosis** : Fractured Left subcondyle with displacement, Right parasymphysis of mandible, Left zygomatic arch

**Classification according to Spiessl and Schroll (1972) : Type - II**

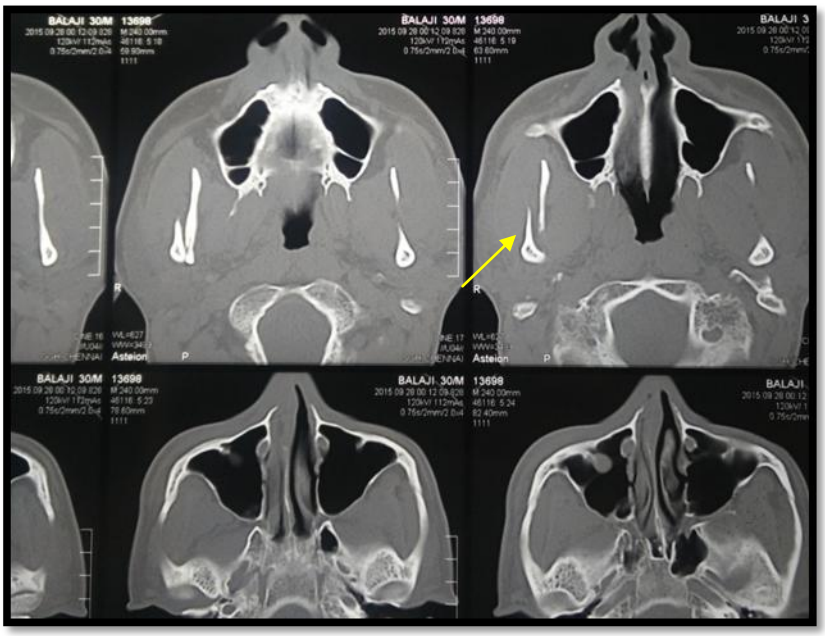
**Treatment plan** : ORIF under GA

**Preoperative**

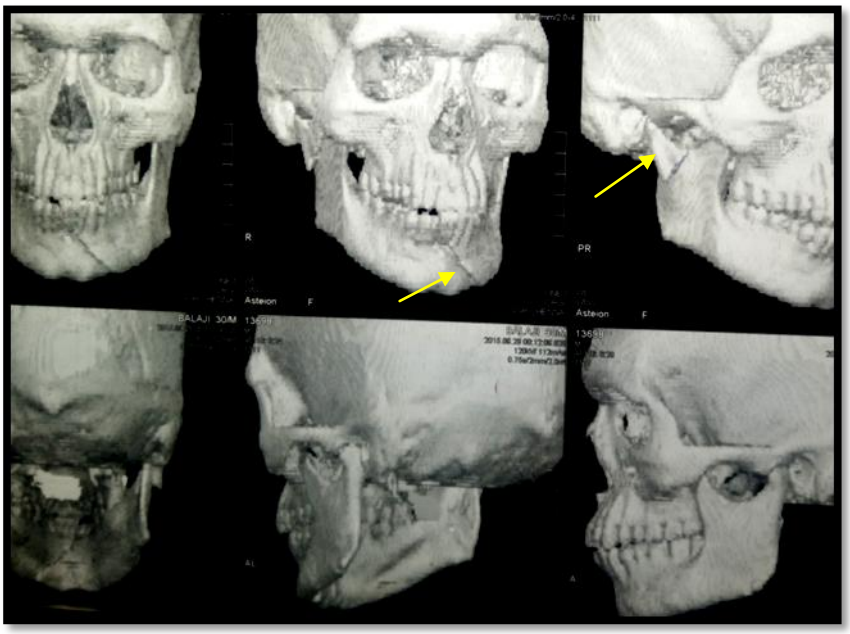
**Preoperative Mouth opening interincisal**

**Preoperative occlusion**

## Preop CT scan




## Preop CT with 3D reconstruction



**Surgical photos - Reduction of fracture**

**Plating with 3D Titanium Trapezoidal plates**

**Preop OPG**

**Immediate Post op OPG**

**6 months Post op OPG**

**Post op Occlusion**

**Post op mouth opening with correction of lateral deviation**

## STATISTICAL ANALYSIS

Data collected was analysed using S.P.S.S. (Statistical Package for social sciences VERSION 16).

## STATISTICAL TESTS USED

Qualitative data: Chi square test [Pearson]

Quantitative data: repeated measures ANOVA

In our prospective clinical and radiological study, we have surgically treated five cases **[n=5]** with subcondylar fractures of mandible. Patients with shortening of ramus height , deviated condylar fractures, impaired dental occlusion and who consented for surgery were taken up for the study.

**Table 1: List Of Fractures**

| Patient | Sub Condyle fracture | Associated fractures |
|---|---|---|
| Patient 1 | Left subcondylar facture | Right parasymphysis |
| Patient 2 | Left subcondylar fracture | Nil |
| Patient 3 | Right subcondylar fracture | Left parasymphysis fracture |
| Patient 4 | Right subcondylar fracture | Right parasymphysis |
| Patient 5 | Left subcondylar fracture | Left zygomatic arch fracture, Right parasymphysis fracture |

All five patients were taken up for ORIF under GA within 1 week of trauma. In all five patients Titanium **3D condylar plates** [2x4 hole] were used for subcondylar fractures and 2x4 hole titanium miniplates with gap for treating associated parasymphyseal fractures. One patient had zygomatic arch fracture which was elevated using Intra oral Keens approach.

In all 5 patients **Retromandibular transmassetric approach** was used for approaching the subcondylar region and Intraoral Paragingival incision for

Parasymphysis fractures. The numbers of dropouts were zero. All the cases were followed up regularly up to six months at regular interval of time.

**PRE-OPERATIVE DEGREE OF CONDYLAR DEVIATION ASSESSMENT**

Pre operatively all the cases underwent radiological assessment using OPG and CT Scans with 3 D reconstruction to assess for the level of subcondyle fracture, degree of deviation of the condyle, reduction in ramus height which served as guideline to evaluate the reduction of fracture postoperatively.

**POST OPERATIVE ASSESSMENT:**

We have followed up the patients, post operatively up to six months period at 1 week, 1 month, 3 months and six months interval.

The following parameters were evaluated both pre and post operatively

I. Mouth opening
II. Mandibular deviation
III. Occlusion
IV. Surgical accessibility
V. Reduction of fracture
VI. Adaptability of 3 dimensional plates
VII. Per operative time
VIII. Post-operative pain
IX. Wound infection
X. Facial nerve weakness
XI. Scar
XII. Osteosynthesis device failure

**MOUTH OPENING**

The maximal interincisal distance was measured using a ruler between upper and lower central incisors both pre and postoperatively and tabulated. They were analysed using chi square test.

Table: 2 Maximal active mouth opening

| In mm | Score |
|---|---|
| >40 mm | 0 |
| 30-39mm | 1 |
| < 30 mm | 5 |

Table 3: n= 5 Mouth opening % of patients

| **Intervals** | **< 30 mm** | **35-40 mm** | **> 40 mm** | **P value** |
|---|---|---|---|---|
| **Pre op** | **100 %** | **0 %** | **0 %** | |
| **1 week** | **0 %** | **60 %** | **40 %** | |
| **1 month** | **0 %** | **0 %** | **100 %** | **0.001*** |
| **3 month** | **0 %** | **0 %** | **100%** | |
| **6 month** | **0 %** | **0 %** | **100 %** | |

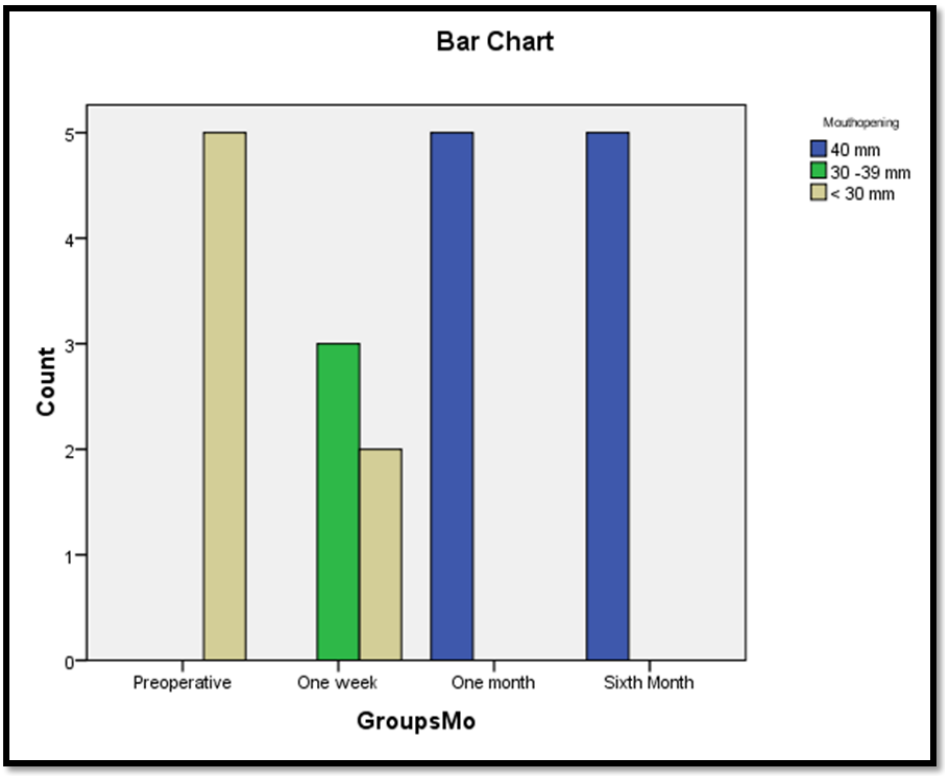
- Pearson chi square test

In our study all patient had mouth opening of < 30 mm preoperatively, and this increased to 30 – 39 mm in the first postoperative week in around 60 % of patients and all patients achieved mouth opening of >40mm by 1 month postoperatively. **The P value was significant P= 0.001 by Pearson Chi square test**.

**Graph: 1 – Mouth opening**

**Y axis – number of patients [n=5]**

**X axis – mouth opening in mm [millimetre]**




40 mm  30 -39 mm  < 30 mm

**MANDIBULAR DEVIATION**

Table: 4 Mandibular Deviation

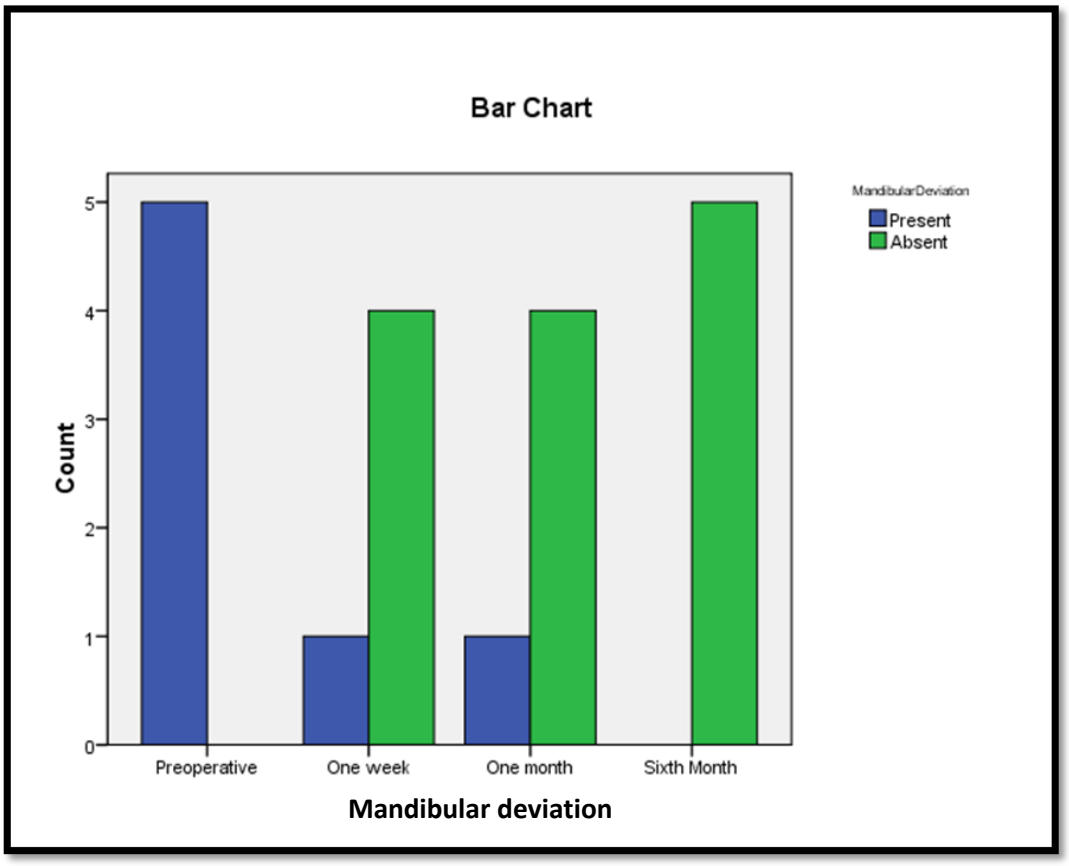
| Intervals | Present | Absent | P value |
|---|---|---|---|
| **Preop** | **100 %** | **0 %** | |
| **1 week** | **20 %** | **80 %** | |
| **1 month** | **20 %** | **80 %** | **0.005** |
| **3 month** | **100%** | **0 %** | |
| **6 month** | **0 %** | **0 %** | |

**All the five patients had lateral deviation preoperatively**. During the first postoperative week 20 % of the patient had lateral deviation, for these patients guiding elastics were placed during the 5th postoperative period and maintained for 10 days and deviation was corrected by 3rd postoperative week. **The P value was significant 0.005**

**Graph 2: Mandibular Deviation**

**X axis – mandibular deviation**

**Y axis – number of patients**




Present

Absent

**OCCLUSION**

Table 5: Occlusion

| Intervals | Present | Absent | P value |
|---|---|---|---|
| **Preop** | **100 %** | **0 %** | **0.005*** |
| **1 week** | **20 %** | **80 %** | |
| **1 month** | **20 %** | **80 %** | |
| **3 month** | **100%** | **0 %** | |
| **6 month** | **0 %** | **0 %** | |

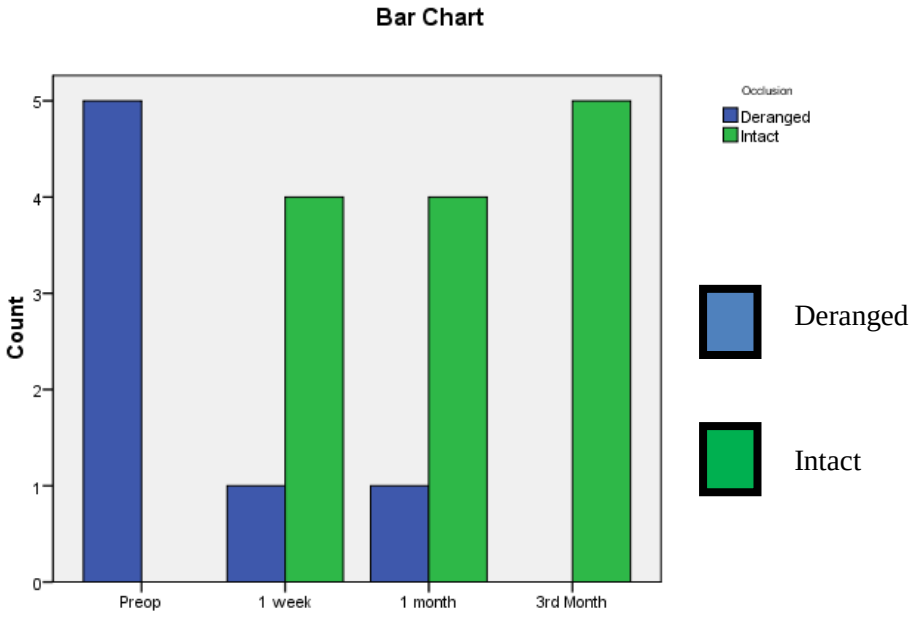
***pearson chi square test**

**All the five patients had occlusal derangement preoperatively**. During the first postoperative week 20 % of the patient had mild occlusal discrepancies. For these patients intermaxillary elastics were placed in the immediate post operative period for 10 days and satisfactory occlusion was achieved by postoperative month. **The P value was significant 0.005**

**Graph: 3 Occlusion**

**X axis - occlusion**

**Y axis – number of patients**

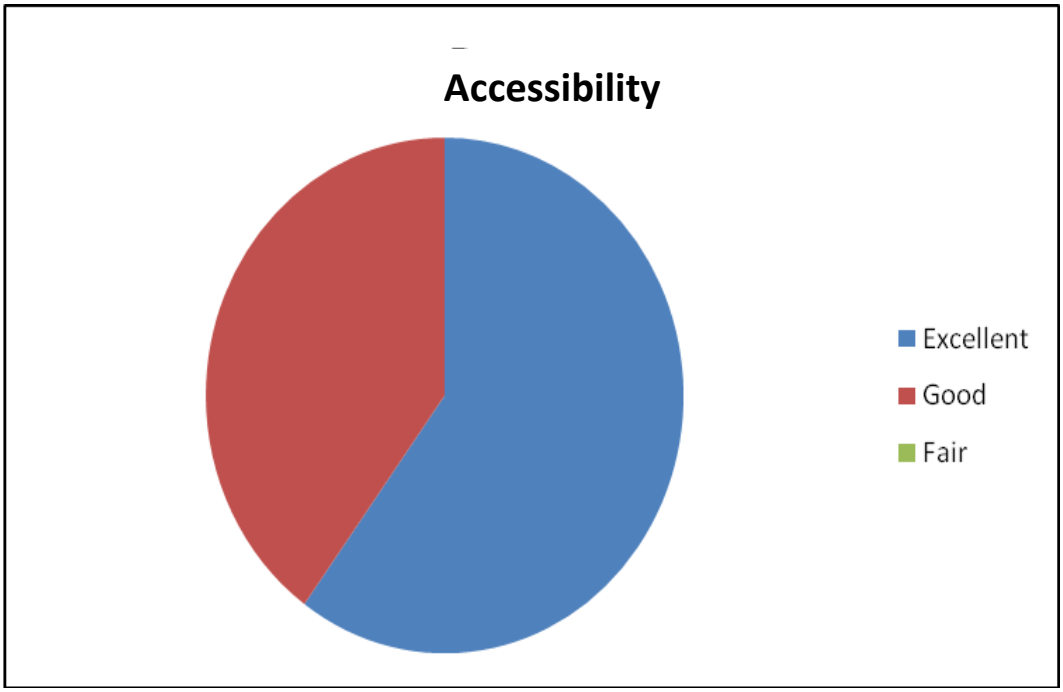


**SURGICAL ACCESSIBILITY**

In all the 5 patients **Retromandibular Transmassetric approach** was used for accessing the fracture. The surgical accessibility was mainly evaluated subjectively by the operating surgeon. In two patients, the accessibility was good due to more medial displacement of the condylar fragment. In other patients the accessibility was **good to excellent.**

Table 6: Surgical Accessibility

| Surgical accessibility | Percent |
|---|---|
| **Excellent** | **60%** |
| **Good** | **40 %** |
| **Fair** | **0 %** |

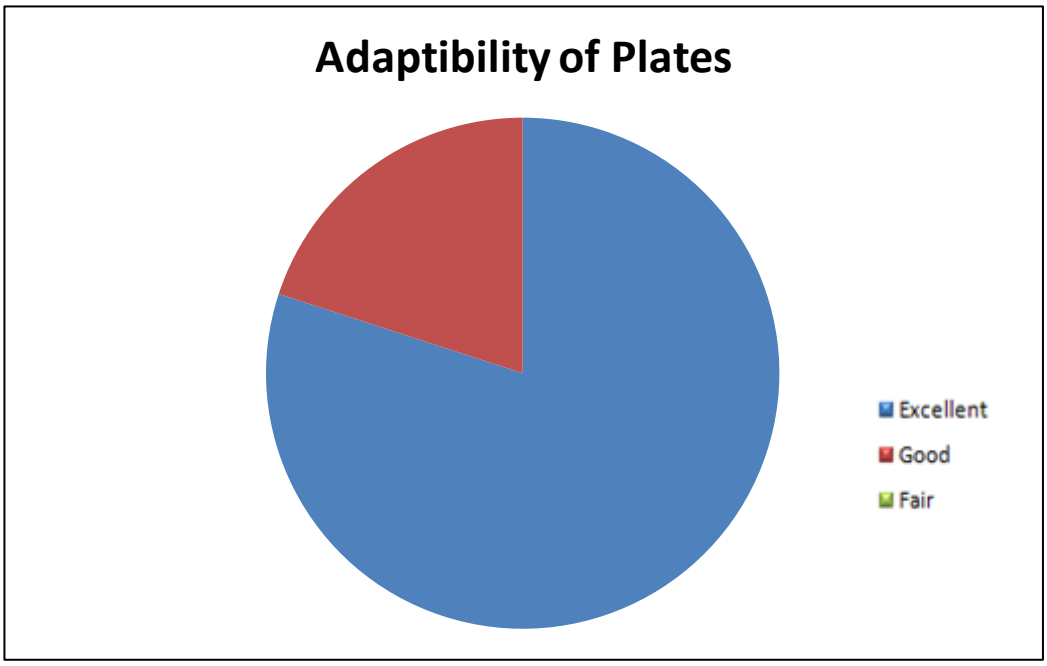


## ADAPTABILITY OF 3D PLATES

Table 7: Adaptability Of 3d Plates

| Adaptability of 3D plates | Percent |
|---|---|
| **Excellent** | **60%** |
| **Good** | **40 %** |
| **Fair** | **0 %** |

In 60% of patients the adaptability was excellent and in 40% it was good due to the presence of severely displaced fractures in the subcondylar region

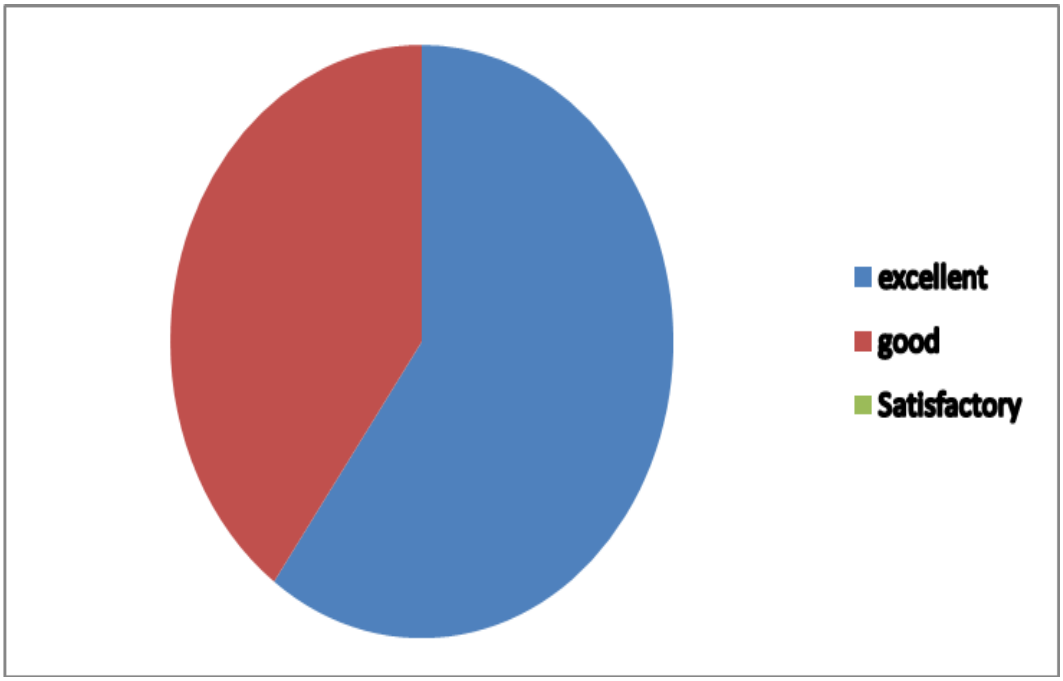


**REDUCTION OF FRACTURED FRAGMENTS**

Table 8: Reduction of Fractured Fragments

| Reduction of fracture | Percent |
|---|---|
| **excellent** | **60%** |
| **good** | **40 %** |
| **Satisfactory** | **0 %** |

**REDUCTION OF FRACTURED FRAGMENTS**



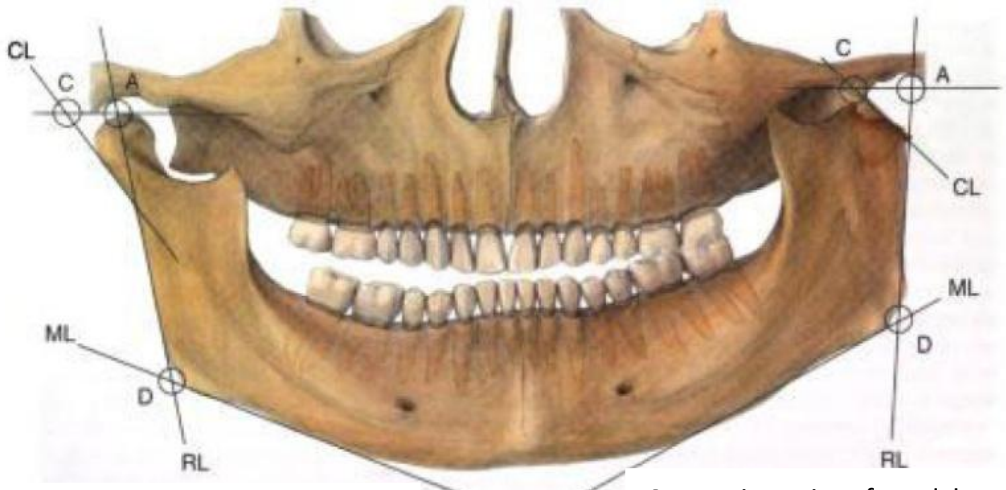

**This was assessed both intra operatively and radiographically.** Displacement in the pre-treatment OPG was measured as **the angle between a line drawn between the medial and lateral poles of the condyle and a tangent through the lateral surface of the mandibular ramus**. The difference between the angle on the non-fractured and the fractured sides was used as a measure of displacement (Palmieri, Ellis et al. 1999) and was taken into consideration for assessing the reduction of fractured fragments.

**Preop OPG**

**Immediate Post op OPG**

**6 months Postop OPG**

**SHORTENING IN HEIGHT OF RAMUS FOR ASSESSING REDUCTION OF FRACTURE**




**ML**- Mandibular line

**RL** – Ramus line

**A**-superior point of condyle

**D**-prominent point of angle

Fig. 11.1 **The method of radiologic measurement.** Ramal height is the distance between the mandibular line (ML) and a tangent to the superior point of the condyle (CA) measured along the ramus line (RL) on the fractured and non-fractured sides (from point A to point D). Reduction of ramus height is represented by the difference in length between the fractured and non-fractured sides. Mandibular line is the tangent to the lower border of the mandible

**[From Härle et al, Atlas of Craniomaxillofacial Osteosynthesis, 1999, Thieme]**

In the OPG, the displacement of the upper fragment in the anterior - posterior direction was investigated, **and the reduction of the ramus height was measured by the difference in length between the fractured and non-fractured side**. The radiographic magnification factor was not taken into account in the measurements, because this examination involves comparative measurements.

The ramus height is calculated as a distance on the **ramus tangent (RL) between the broadest part of condylar head and most inferior contact of line (RL) to the angle of the mandible**. The difference between the non fractured and the fractured sides was used as a measure of difference in ramus length. In cases

of bilateral fracture, the amount of overlay was measured to assess the amount of shortening**.**

**Table 9:**

| | Difference in ramus length [mm] Mean ±SD | Angulation mean±SD[degrees] |
|---|---|---|
| Pre op | 8.4± 4.2mm | 21.8±19.2 º |
| Post op | -0.2mm±1.4mm | 0.0±1.2 º |
| P value | **0.009*** | **0.016*** |

*pearson chi square test

The average postoperative shortening of the ascending ramus height compared with non-fractured side was less than -0.2 mm (range, 0 to 3 mm; SD 1.4). **This was statistically significant with a P value of 0.009**

**Preoperative OPG**

**Post op OPG**

**PER-OPERATIVE TIME**

This was measured in minutes from starting of incision to closure of wound. The preoperative time varied, with the presence of associated fractures of mandible. The average preoperative time was **61min with SD± 11.6min.** The operating time in isolated condylar fracture was **45 minutes.**

Table 10: Per-Operative Time

| | **Duration of surgery [mins]** |
|---|---|
| **Patient 1** | **45** |
| **Patient 2** | **57** |
| **Patient 3** | **68** |
| **Patient 4** | **60** |
| **Patient 5** | **76** |

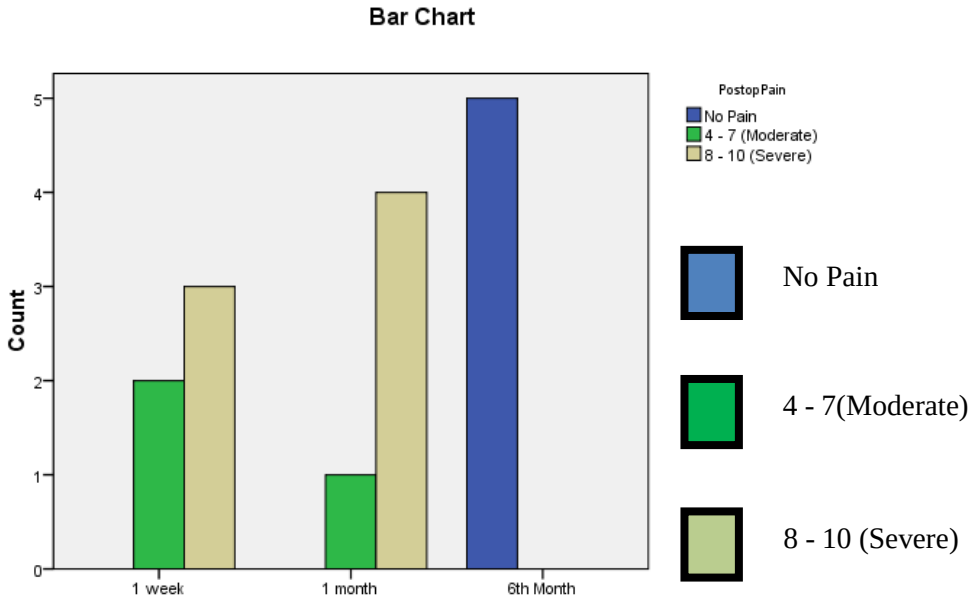
**POSTOPERATIVE PAIN**

Table 11: Postoperative Pain

| **intervals** | **No pain** | **Moderate** | **Severe** | **P value** |
|---|---|---|---|---|
| **1 week** | **0 %** | **66.7 %** | **42.9 %** | **0.003** |
| **1 month** | **0 %** | **33.3 %** | **57.1 %** | |
| **6 month** | **0 %** | **0 %** | **0%** | |

The postoperative pain was measured using VAS scale (visual analog scale) from 0 to 10. 66.7 % of the patients had moderate intensity pain during the first week postoperatively**. At the end of six months, all patients were pain free on maximum mouth opening, lateral excursion and protrusive movements**.

The results were **statistically significant with the P value of 0.003 with Pearson chi square index**.




**SCAR**

Table 12: SCAR

| | | |
|---|---|---|
| Conspicuous | Visible but thin and linear | P value – 0.005 |
| Inconspicuous | No noticeable scar | |
| Hypertrophic | scar > 1mm in elevation | |

Table 12 B:

| | 1 week | 1 month | 6th month |
|---|---|---|---|
| Patient 1 | 3 | 3 | 3 |
| Patient | 3 | 3 | 2 |
| Patient 3 | 3 | 3 | 2 |
| Patient 4 | 3 | 3 | 2 |
| Patient 5 | 3 | 3 | 2 |

In all the other patients the scar was conspicuous during 1 and 3 postoperative month and became inconspicuous by 6 postoperative month. The results were **statistically significant with a P value of 0.005.**

**COMPLICATIONS**

**POSTOPERATIVE HEMATOMA**

One patient had postoperative hematoma which subsided by fifth postoperative day.

**Present - 1**

**Absent – 2**

Table 13: Postoperative Hematoma

| | Present | Absent |
|---|---|---|
| Patient 1 | | 2 |
| Patient | 1 | |
| Patient 3 | | 2 |
| Patient 4 | | 2 |
| Patient 5 | | 2 |
| Patient 6 | | 2 |

**WOUND INFECTION**

The wound infection was assessed by the presence of discharge / pus from the surgical site one patient had wound infection during second postoperative week which was managed by appropriate oral antibiotics which subsided within five days. Since it was only a superficial infection involving only skin and subcuticular layer, no incision and drainage or revision of surgery was required.

**Present – 1**

**Absent – 2**

Table 13: Wound Infection

| | 1 week post op | | 1 month post op | | 6th month post op | |
|---|---|---|---|---|---|---|
| | present | absent | present | absent | present | absent |
| Patient 1 | 1 | | | 2 | | 2 |
| Patient 2 | | 2 | | 2 | | 2 |
| Patient 3 | | 2 | | 2 | | 2 |
| Patient 4 | | 2 | | 2 | | 2 |
| Patient 5 | | 2 | | 2 | | 2 |

**FACIAL NERVE WEAKNESS**

In one patient postoperative weakness of marginal mandibular branch of facial nerve was observed during active mouth puckering and downward movement of affected corner of the mouth. Weakness of facial nerve lasted for 2 months . After 6 months permanent disturbance of the facial nerve was not present. However it was not statistically significant.

Paresthesia / paralysis – present or absent [branches of facial nerve ]

**Present -1**

**Absent -2**

Table 14 : Facial Nerve Weakness

| | preoperative | | 1 week | | 1 month | | 3rd month | | 6th month | |
|---|---|---|---|---|---|---|---|---|---|---|
| | present | absent | present | absent | Present | absent | present | Absent | present | absent |
| Patient 1 | | 2 | 1 | | 1 | | | 2 | | 2 |
| Patient 2 | | 2 | | | | 2 | | 2 | | 2 |
| Patient 3 | | 2 | | | | 2 | | 2 | | 2 |
| Patient 4 | | 2 | | | | 2 | | 2 | | 2 |
| Patient 5 | | 2 | | | | 2 | | 2 | | 2 |

**OSTEOSYNTHESIS DEVICE FAILURE**

Assessed by

1. Plate bending
2. Plate fracture
3. Screw loosening

**None of patients presented with osteosynthesis device failure during the 6 months postoperative period which was evaluated in the sequential OPG was taken.**

Plate fracture / plate bending/screw loosening

**Present -1**

**Absent -2**

Table 15: Osteosynthesis Device Failure

| | 1 week | | 1 month | | 3 month | |
|---|---|---|---|---|---|---|
| | present | absent | present | absent | present | Absent |
| Patient 1 | | 2 | | 2 | | 2 |
| Patient 2 | | 2 | | 2 | | 2 |
| Patient 3 | | 2 | | 2 | | 2 |
| Patient 4 | | 2 | | 2 | | 2 |
| Patient 5 | | 2 | | 2 | | 2 |

Mandibular fractures comprises of around 65-70 % of all maxillofacial trauma and with only the mandible being fractured in 50% of the cases [Becker R, 1973]. During last 25 years condyle fractures comprise 17.5%-52% of all mandibular fractures. **Widmark**[74] and **Santler**[75] have documented that mandibular condylar process is the most common fracture of the maxillofacial region. Due to its peculiar anatomic and functional features unlike the other joints, fractures of condyle requires skilled management to re-establish the anatomical and biofunctionality of the joint and the harmony of the associated osseous and soft tissue structures.

Open reduction of condylar fractures is one of the most debated topics among the maxillofacial surgeons worldwide. A condylar fracture with loss of vertical ramus height associated with or without dislocation of the disco- condylar unit is now generally accepted as an indication for open reduction and internal fixation. **Walker et al 1994**[76] described the goals for management of condylar fractures. These included pain free movement of the mandible, good occlusion, symmetry of mandibular movements.

Besides selecting the most appropriate surgical approach, it becomes equally important to select an appropriate osteosynthesis device that can withstand and transmit the functional load applied to it, in an anatomically and biomechanically complex area like the condylar region. From the biomechanical point of view, factors such as buttressing effect, loss of bone in the fracture gap or presence of comminuted fractures play a considerable impact on the primary and secondary stability of the osteosynthesis device.

Human mandible is shown to exhibit numerous complex combination of movements and torsion patterns, which must be considered when evaluating the stability of the osteosynthesis device[77]. Also miniature osteosynthesis devices become essential for stabilization of subcondylar fractures because of the usually small size of condylar fragments. It is also mandatory to place these plates along "Ideal line of osteosynthesis'' for dictating predictable outcome. **Champy et al 1976**[6] experimentally located these strain lines in the mandibular body, symphysis and angle region. Later **Meyer et al**[7] proposed ideal lines of osteosynthesis in condylar region.

**Choi et al**[34] reported superior biomechanical stability of the double monocortical miniplate technique when compared to other plating techniques for condylar fractures. The main factor affecting the stability of osteosynthesis of condylar neck are incongruent reduction of fracture gaps due to inadequate adaptation of plates. The gaps between the fractured segments after reduction have considerable effect on the stability of the plate.

The double mini plating technique, although the most widely accepted and used for subcondylar fracture, the surgeon is confronted with the problem of restricted visualisation of the condylar neck area, which impedes a correct anatomic reduction and plate adaptation. Many authors have reported high failure rate associated with double plating technique of upto 35 % including plate fractures.[65, 75, 78]

**Meyer et al 2006 a**[22] demonstrated experimentally that the use of double plating in many instances does not provide sufficient strength to withstand the

physiological strain in the subcondylar region during function. He tested three osteosynthesis devices and found that none of the tested devices fulfilled the principles of functionally stable osteosynthesis [**Champy et al 1976, Meyer et al 2002**] resulting in instability or plate fracture[79].

This became the starting point that led to the development of **Trapezoidal condylar plates – 3D** [Medartis, Switzerland], designed specifically for use in low and high subcondylar fractures. The Trapezoidal plates are designed in accordance with the findings of invitro analysis of load, strain and bone deformation at the condyle.

**During functional activity there are tensile strains at the antero - lateral border, compressive strain along the posterior-medial border and permanent latero medial bending of the condyle[4]**. These principles mandate that, in order to provide the best possible bio functionality, the plates must be placed along the ideal lines of osteosynthesis. The plate is trapezoidal in shape, so that the anterior arm of the plate can be superimposed over the tension lines under the sigmoid notch. Because of their grids form, the TCP plates belong to 3D plates which were developed by **Farmard[46]** in nineties. The 3D plates were developed to offer

- Enhanced stability
- Less periosteal destruction
- Osteosynthesis of small fragments
- Minimum osteosynthesis material
- Ease of placement

**In this study we aimed at evaluating the efficacy of these 3D plates and its effectiveness in subcondylar fractures of mandible by assessing various parameters.**

Out of 5 patients 4 were associated with Parasymphyseal fractures. **Sawazaki, Lima Junior et al 2010[79]** reported that subcondylar fractures results mainly due to tensile failure via distributed indirect impact leading to extreme bending of the mandibular neck as one of the weakest points in the mandible. This mechanism explains the correlation between symphyseal fractures and condylar fractures.

The mean amount of maximal active interincisal opening was 41.6 mm (range 30 to 60, SD ±2.1mm). This value was acceptable in comparison to a **Landes and Sader 2007**[80]

**Measuring lateral movements of the mandible are better indicators** than mouth opening in evaluating the functional ability of TMJ because these measurements are ideal for assessing translational motions of the condyle which could be affected to a greater degree through the damage of TMJ caused by fractures. [**Buschang, Throckmorton et al. 2000]**[81].

In this study group, the lateral protrusive movements were within normal range without significant difference between the fractured and non fractured side by 3rd post operative month, consistent with the results of another study [**Trost, Trouilloud et al. 2009**][82].

One of the most important criteria of treatment of subcondyle fracture is restoring the pretraumatic occlusal relationship. In literature percentages of post ORIF malocclusion vary widely. This may be attributed to the patient's previous dental status, presence of additional fracture in the maxillofacial region, bilateral condylar fractures, inadequate reduction of the fractured fragments [**Ellis, 1998] Meyer, Zink et al. 2008]**[83]**.**

In this study no occlusal disturbances was noted at 6 months follow up consistent with findings of **Ellis et al 2000**[84].

Accessibility is measured by the duration of the procedure, ability to reduce the fracture, ease of placement of plates and screws , with preservation of facial nerve. In this study **retromandibular transmassetric approach was used** which provided good surgical access to the subcondylar region, consistent with results of **Federico Biglioli, et al 2009**[85]

In this study, it was found that it is easier to adapt the 3D plates in subcondylar region along the lines of osteosynthesis which may be attributed to its geometric configuration which is similar to reports of **Meyer et al 2008**[83] Reduction of fracture after placement of the 3D plates was excellent to good, consistent with studies by **Meyer et al 2008**[83].

Radiographic evaluation demonstrated good accuracy of anatomic reduction in all cases. Postoperatively, the mean difference in ramus height was -0.2mm±SD1.4mm and angulation 0.0º±SD1.2º was comparable to the study performed by **Singh et al**[86] [0.38mm, 1.1º].

In this study one patient had an unesthetic scar. **Ellis et al**[87] reported unesthetic scars in 7.5% of cases in their cohort of 93 patients. **Meyer et al** in their study has reported wound infection rate of 1.45 %. One patient had superficial wound infection which may be probably attributed to contamination from intraoral wound site despite the aseptic precautions taken.

There was no radiographic evidence of plate bending, screw loosening or plate fracture during the 6 months follow up period similar to reports of **Meyer et al 2008**[83].

Closed reduction of condylar fractures leads to occlusal discrepancies, deviation on mouth opening, shortening of ramus leading to long term TMJ problems. With advancements in surgery and anaesthesia, today the most widely accepted treatment for subcondylar fractures is open reduction and internal fixation. But it is very crucial to select an appropriate osteosynthesis device to dictate the most predictable outcome and to avoid complications.

The anatomy and biomechanics of condylar region portrays varying degrees of stress and compressive forces acting during functional load. So the osteosynthesis device should be able to fulfil the following, in order for it to function efficiently.

1. Adaptation in the anatomically constricted region of condylar neck.
2. Placement parallel to the condylar axis and parallel to the mandibular notch **[ along lines of osteosynthesis ]**
3. Resisting the forces in three dimensions namely shearing, bending, and torsional forces.
4. Minimal dissection
5. Semi rigid fixation with lesser complications
6. Reduced hardware.

**Titamium 3D first developed by Farmand** to meet the requirements of semi rigid fixation with lesser complications for mandibular fractures. This was used by **Meyer et al** for treating condylar fracture. The geometric form of the trapezoidal [3D plates] is designed with an idea to resist forces in three dimensions namely bending, shearing and torsion.

The quadrangular shape allows for placing one arm parallel to condylar axis and the other arm under the sigmoid notch [**lines of osteosynthesis in condyle – Meyer et al 2000].**

This is a prospective study conducted at THE TAMILNADU GOVERMENT DENTAL COLLEGE AND HOSPITAL, CHENNAI in which 5 patients with subcondylar fractures were treated by ORIF under GA.

In all five patients, clinically in the immediate postoperative period, there was increase in

- Mouth opening,
- Reduced mandibular deviation,
- Correction of occlusion to pretraumatic level and

  Radiographically there was
- Restoration of ramus height,
- Correction of angulation,
- Good reduction of fracture , and the P value was significant <0.005

None of the patients required postoperative IMF and soft diet was started on the first postoperative day. All these factors improved patient compliance and satisfaction.

One patient had weakness of marginal mandibular nerve initially and no weakness at 6 months postoperatively. This may be due to retraction intraoperatively. All patients except one were satisfied with the appearance of scar at the end of 6 months. None of the patients reported with clicking or TMJ pain at the end of 6 months.

There was no evidence of any osteosynthesis device failure radiographically and clinically at the end of follow up period. The results of this study concurred with study done by **Meyer et al 2008.**

## CONCLUSION

**From our results of 5 cases, we conclude that the 3 D trapezoidal plates is effective in treating subcondylar fractures of mandible , both in terms of surgical accessibility and stability.**

The small sample size and limited follow-up could be considered as the limitations of this study.

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**ANNEXURE I**

**CASE REPORT FORM**

"**EVALUVATION OF 3 DIMENSIONAL PLATES IN OPEN REDUCTION AND INTERNAL FIXATION OF SUBCONDYLAR FRACTURES**"

Patient's Name : _____

Age/ Sex : _____

Patient's Identification No : _____

_____

Contact Address : _____

Contact No : _____

Institution : TN Govt. Dental College & Hospital,

Chennai - 600 003.

Centre : Dept. of Oral & Maxillofacial Surgery,

TN. Govt. Dental College and Hospital,

Chennai - 600 003.

Patient'sIdentification/ O PNo : _____ Date: _____

Details of Surgery

Procedure followed : Open reduction and internal fixation under GA

Duration of Surgery :

Any other information :

Details of Drug therapy :

Name of the Investigator :

Signature of Investigator :

**ANNEXURE II**

**CASE SHEET**

"**EVALUVATION OF 3 DIMENSIONAL PLATES IN OPEN REDUCTION AND INTERNAL FIXATION OF SUBCONDYLAR FRACTURES**"

PATIENT'S NAME : _____

AGE/ SEX : _____

PATIENT'S : _____

IDENTIFICATION NO : _____

CONTACT ADDRESS : _____

_____

CONTACT No : _____

INSTITUTION : TN Govt. Dental College & Hospital,
Chennai - 600 003.

CENTRE : Dept. of Oral & Maxillofacial Surgery,
TN. Govt. Dental College and Hospital,
Chennai - 600 003.

CHIEF COMPLAINT:

HISTORY:

CLINICAL FINDINGS:

INVESTIGATIONS:

TREATMENT:

Procedure followed : Open reduction and internal fixation

Duration of surgery :

FOLLOW UP

NAME OF THE INVESTIGATOR :

SIGNATURE OF INVESTIGATOR

**ANNEXURE III**

**INFORMED CONSENT**

"**EVALUVATION OF 3 DIMENSIONAL PLATES IN OPEN REDUCTION AND INTERNAL FIXATION OF SUBCONDYLAR FRACTURES''**

Participant ID No:

"I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care."

| Date | Name of the participant | Signature/thumb impression of the participant |
|---|---|---|

***[The literate witness selected by the participant must sign the informed consent form. The witness should not have any relationship with the research team; If the participant doesn't want to disclose his / her participation details to others, in view of respecting the wishes of the participant, he / she can be allowed to waive from the witness procedure (This is applicable to literate participant ONLY). This should be documented by the study staff by getting signature from the prospective participant]***

_____

_____

"I have witnessed the accurate reading of the consent form to the potential participant and the individual has had opportunity to ask questions. I confirm that the individual has given consent freely"

| Date | Name of the witness | Signature of the witness |
|---|---|---|

| Date | Name of the interviewer | Signature of the interviewer |
|---|---|---|

## ANNEXURE IV

# ஆராய்ச்சி ஒப்புதல் படிவம்

**ஆராயச்சியின் தலைப்பு**

**கீழ்தாடை முனையெலும்பு முறிவை முப்பரிமான தட்டுகள் கொண்டு அறுவை சிகிச்சை மூலம் சரிசெய்தல் – ஒரு ஆய்வு.**

பெயர் புறநோயாளி எண்

வயது/ பால் ஆராய்ச்சி சேர்க்கை எண்

முகவரி

தொலைபேசி

நான் ..... வயது ..... என்னுடைய சுய நினைவுடனும் மற்றும் முழு சுதந்திரத்துடனும் இந்த மருத்துவ ஆராய்ச்சியில் என்னை சேர்த்துக்கொள்ள ஒப்புதல் அளிக்கிறேன்.

**கீழ்காணப்படும் நிபந்தனைகளுக்கு நான் சம்மதிக்கிறேன்.**

நான் இந்த ஆராய்ச்சியின் நோக்கம் மற்றம் செயல்முறைகள் பற்றி முழுமையாக தெரிவிக்கப்பட்டுள்ளேன்.

இந்த பரிசோதனைக்காக எனது முறிந்த கீழ்தாடையின் முனை எலும்பு முப்பரிமான தட்டுகள் கொண்டு சரிசெய்வதற்கான அறுவை சிகிச்சை மேற்கொள்ளப்படும் என்பதை அறிவேன்.

என் உடல் நலம் பாதிக்ப்பட்டாலோ அல்லது எதிர்பாராத வழக்கத்திற்கு மாறான நோய்குறிகள் தென்பட்டாலோ அதற்கு சிகிச்சை பெற்றுக்கொள்வதற்கும் முழு உரிமை உள்ளதாக அறிகிறேன்.

நான் ஏற்கனவே உட்கொண்ட மற்றும் உட்கொள்கின்ற மருந்துகளின் விபரங்களை ஆராய்ச்சியாளரிடம் தெரிவித்துள்ளேன்.

என் மருத்துவ குறிப்பேடுகளை இந்த ஆராய்ச்சியில் பயன்படுத்திக்கொள்ள சம்மதிக்கிறேன். இந்த ஆராய்ச்சி மையமும் ஆராய்ச்சியாளரும் என்னுடைய விபரங்கள் அனைத்தையும் இரகசியமாக வைப்பதாக அறிகிறேன்.

| ..... | ..... | ..... |
|---|---|---|
| நேயாளியின் பெயர் | கையொப்பம் | தேதி |
| ..... | ..... | ..... |
| ஆராய்ச்சியாளர் பெயர் | கையொப்பம் | தேதி |